## 表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

MCH

| | Baseline | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Placebo (N=97) | | | | TAK-385 10mg (N=103) | | | | TAK-385 20mg (N=100) | | | | TAK-385 40mg (N=103) | | | | Leuprorelin (N=80) | | | |
| Visit | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total |
| Week 4 | | | | | | | | | | | | | | | | | | | | |
| Low | 13 | 1 | - | 14 | 9 | 1 | - | 10 | 14 | 1 | - | 15 | 19 | 2 | - | 21 | 13 | - | - | 13 |
| Normal | 1 | 82 | - | 83 | 2 | 91 | - | 93 | 1 | 84 | - | 85 | 3 | 79 | - | 82 | 1 | 66 | - | 67 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 14 | 83 | - | 97 | 11 | 92 | - | 103 | 15 | 85 | - | 100 | 22 | 81 | - | 103 | 14 | 66 | - | 80 |
| Week 8 | | | | | | | | | | | | | | | | | | | | |
| Low | 13 | 1 | - | 14 | 8 | - | - | 8 | 13 | 1 | - | 14 | 14 | 1 | - | 15 | 12 | 2 | - | 14 |
| Normal | 1 | 80 | - | 81 | 3 | 92 | - | 95 | 2 | 80 | - | 82 | 8 | 78 | - | 86 | 2 | 62 | - | 64 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 14 | 81 | - | 95 | 11 | 92 | - | 103 | 15 | 81 | - | 96 | 22 | 79 | - | 101 | 14 | 64 | - | 78 |
| Week 12 | | | | | | | | | | | | | | | | | | | | |
| Low | 12 | 1 | - | 13 | 9 | 1 | - | 10 | 11 | 2 | - | 13 | 11 | - | - | 11 | 12 | 1 | - | 13 |
| Normal | 1 | 79 | - | 80 | 2 | 89 | - | 91 | 3 | 76 | - | 79 | 11 | 79 | - | 90 | 2 | 60 | - | 62 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 13 | 80 | - | 93 | 11 | 90 | - | 101 | 14 | 78 | - | 92 | 22 | 79 | - | 101 | 14 | 61 | - | 75 |
| Week 16 | | | | | | | | | | | | | | | | | | | | |
| Low | 11 | 3 | - | 14 | 7 | 1 | - | 8 | 9 | 1 | - | 10 | 8 | 1 | - | 9 | 7 | 1 | - | 8 |
| Normal | 1 | 60 | - | 61 | 2 | 74 | - | 76 | 3 | 65 | - | 68 | 11 | 69 | - | 80 | 5 | 56 | - | 61 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 12 | 63 | - | 75 | 9 | 75 | - | 84 | 12 | 66 | - | 78 | 19 | 70 | - | 89 | 12 | 57 | - | 69 |
| Week 20 | | | | | | | | | | | | | | | | | | | | |
| Low | 11 | 4 | - | 15 | 6 | 1 | - | 7 | 8 | 3 | - | 11 | 5 | - | - | 5 | 6 | 1 | - | 7 |
| Normal | 1 | 59 | - | 60 | 3 | 71 | - | 74 | 4 | 62 | - | 66 | 14 | 68 | - | 82 | 6 | 52 | - | 58 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 12 | 63 | - | 75 | 9 | 72 | - | 81 | 12 | 65 | - | 77 | 19 | 68 | - | 87 | 12 | 53 | - | 65 |
| Week 24 | | | | | | | | | | | | | | | | | | | | |
| Low | 10 | 5 | - | 15 | 3 | 2 | - | 5 | 8 | 4 | - | 12 | 6 | - | - | 6 | 6 | - | - | 6 |
| Normal | 1 | 52 | - | 53 | 5 | 69 | - | 74 | 4 | 60 | - | 64 | 13 | 69 | - | 82 | 6 | 50 | - | 56 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 11 | 57 | - | 68 | 8 | 71 | - | 79 | 12 | 64 | - | 76 | 19 | 69 | - | 88 | 12 | 50 | - | 62 |
| Follow-up | | | | | | | | | | | | | | | | | | | | |
| Low | 11 | 8 | - | 19 | 4 | 1 | - | 5 | 6 | 4 | - | 10 | 6 | 1 | - | 7 | 5 | - | - | 5 |
| Normal | 1 | 57 | - | 58 | 5 | 73 | - | 78 | 6 | 61 | - | 67 | 13 | 69 | - | 82 | 7 | 57 | - | 64 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 12 | 65 | - | 77 | 9 | 74 | - | 83 | 12 | 65 | - | 77 | 19 | 70 | - | 89 | 12 | 57 | - | 69 |

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

## 表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

MCHC

| | Baseline | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Placebo (N=97) | | | | TAK-385 10mg (N=103) | | | | TAK-385 20mg (N=100) | | | | TAK-385 40mg (N=103) | | | | Leuprorelin (N=80) | | | |
| Visit | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total |
| Week 4 | | | | | | | | | | | | | | | | | | | | |
| Low | 4 | - | - | 4 | 5 | 2 | - | 7 | 6 | 2 | - | 8 | 7 | 1 | - | 8 | 10 | 2 | - | 12 |
| Normal | 3 | 90 | - | 93 | 3 | 93 | - | 96 | 1 | 91 | - | 92 | 7 | 88 | - | 95 | 1 | 67 | - | 68 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 7 | 90 | - | 97 | 8 | 95 | - | 103 | 7 | 93 | - | 100 | 14 | 89 | - | 103 | 11 | 69 | - | 80 |
| Week 8 | | | | | | | | | | | | | | | | | | | | |
| Low | 3 | 2 | - | 5 | 4 | 5 | - | 9 | 6 | 2 | - | 8 | 6 | 1 | - | 7 | 9 | - | - | 9 |
| Normal | 4 | 86 | - | 90 | 4 | 90 | - | 94 | 1 | 87 | - | 88 | 8 | 86 | - | 94 | 2 | 67 | - | 69 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 7 | 88 | - | 95 | 8 | 95 | - | 103 | 7 | 89 | - | 96 | 14 | 87 | - | 101 | 11 | 67 | - | 78 |
| Week 12 | | | | | | | | | | | | | | | | | | | | |
| Low | 3 | 5 | - | 8 | 4 | 2 | - | 6 | 2 | 2 | - | 4 | 6 | - | - | 6 | 7 | - | - | 7 |
| Normal | 3 | 82 | - | 85 | 4 | 91 | - | 95 | 5 | 83 | - | 88 | 8 | 87 | - | 95 | 4 | 64 | - | 68 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 6 | 87 | - | 93 | 8 | 93 | - | 101 | 7 | 85 | - | 92 | 14 | 87 | - | 101 | 11 | 64 | - | 75 |
| Week 16 | | | | | | | | | | | | | | | | | | | | |
| Low | 2 | 3 | - | 5 | 3 | 1 | - | 4 | 2 | - | - | 2 | 5 | 1 | - | 6 | 4 | - | - | 4 |
| Normal | 3 | 67 | - | 70 | 3 | 77 | - | 80 | 4 | 72 | - | 76 | 7 | 76 | - | 83 | 6 | 59 | - | 65 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 5 | 70 | - | 75 | 6 | 78 | - | 84 | 6 | 72 | - | 78 | 12 | 77 | - | 89 | 10 | 59 | - | 69 |
| Week 20 | | | | | | | | | | | | | | | | | | | | |
| Low | 3 | 4 | - | 7 | 2 | 2 | - | 4 | 2 | 1 | - | 3 | 5 | - | - | 5 | 3 | - | - | 3 |
| Normal | 2 | 66 | - | 68 | 4 | 73 | - | 77 | 4 | 70 | - | 74 | 7 | 75 | - | 82 | 7 | 55 | - | 62 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 5 | 70 | - | 75 | 6 | 75 | - | 81 | 6 | 71 | - | 77 | 12 | 75 | - | 87 | 10 | 55 | - | 65 |
| Week 24 | | | | | | | | | | | | | | | | | | | | |
| Low | 3 | 3 | - | 6 | 2 | 1 | - | 3 | 2 | - | - | 2 | 4 | - | - | 4 | 3 | - | - | 3 |
| Normal | 1 | 61 | - | 62 | 4 | 72 | - | 76 | 4 | 70 | - | 74 | 8 | 76 | - | 84 | 7 | 52 | - | 59 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 4 | 64 | - | 68 | 6 | 73 | - | 79 | 6 | 70 | - | 76 | 12 | 76 | - | 88 | 10 | 52 | - | 62 |
| Follow-up | | | | | | | | | | | | | | | | | | | | |
| Low | 4 | 6 | - | 10 | 2 | 2 | - | 4 | 2 | 2 | - | 4 | 3 | - | - | 3 | 1 | - | - | 1 |
| Normal | 1 | 66 | - | 67 | 4 | 75 | - | 79 | 4 | 69 | - | 73 | 9 | 77 | - | 86 | 9 | 59 | - | 68 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 5 | 72 | - | 77 | 6 | 77 | - | 83 | 6 | 71 | - | 77 | 12 | 77 | - | 89 | 10 | 59 | - | 69 |

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

## 表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

MCV

| | Baseline | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Placebo (N=97) | | | | TAK-385 10mg (N=103) | | | | TAK-385 20mg (N=100) | | | | TAK-385 40mg (N=103) | | | | Leuprorelin (N=80) | | | |
| Visit | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total |
| Week 4 | | | | | | | | | | | | | | | | | | | | |
| Low | 5 | 2 | - | 7 | 6 | - | - | 6 | 6 | 1 | - | 7 | 4 | 2 | - | 6 | 5 | 2 | - | 7 |
| Normal | 1 | 88 | 1 | 90 | - | 96 | - | 96 | 1 | 91 | - | 92 | 1 | 96 | - | 97 | - | 71 | - | 71 |
| High | - | - | - | - | - | - | 1 | 1 | - | - | 1 | 1 | - | - | - | - | - | 2 | - | 2 |
| Total | 6 | 90 | 1 | 97 | 6 | 96 | 1 | 103 | 7 | 92 | 1 | 100 | 5 | 98 | - | 103 | 5 | 75 | - | 80 |
| Week 8 | | | | | | | | | | | | | | | | | | | | |
| Low | 4 | 4 | - | 8 | 5 | - | - | 5 | 7 | 1 | - | 8 | 4 | 1 | - | 5 | 4 | 1 | - | 5 |
| Normal | 2 | 84 | - | 86 | 1 | 96 | 1 | 98 | - | 87 | - | 87 | 1 | 95 | - | 96 | 1 | 72 | - | 73 |
| High | - | - | 1 | 1 | - | - | - | - | - | - | 1 | 1 | - | - | - | - | - | - | - | - |
| Total | 6 | 88 | 1 | 95 | 6 | 96 | 1 | 103 | 7 | 88 | 1 | 96 | 5 | 96 | - | 101 | 5 | 73 | - | 78 |
| Week 12 | | | | | | | | | | | | | | | | | | | | |
| Low | 4 | 4 | - | 8 | 4 | 2 | - | 6 | 7 | 1 | - | 8 | 4 | 1 | - | 5 | 4 | 1 | - | 5 |
| Normal | 1 | 84 | - | 85 | 2 | 92 | 1 | 95 | - | 83 | - | 83 | 1 | 95 | - | 96 | 1 | 69 | - | 70 |
| High | - | - | - | - | - | - | - | - | - | - | 1 | 1 | - | - | - | - | - | - | - | - |
| Total | 5 | 88 | - | 93 | 6 | 94 | 1 | 101 | 7 | 84 | 1 | 92 | 5 | 96 | - | 101 | 5 | 70 | - | 75 |
| Week 16 | | | | | | | | | | | | | | | | | | | | |
| Low | 4 | 4 | - | 8 | 2 | 2 | - | 4 | 4 | 2 | - | 6 | 3 | 1 | - | 4 | 4 | 1 | - | 5 |
| Normal | 1 | 66 | - | 67 | 3 | 76 | - | 79 | 2 | 69 | - | 71 | 2 | 83 | - | 85 | 1 | 63 | - | 64 |
| High | - | - | - | - | - | - | 1 | 1 | - | - | 1 | 1 | - | - | - | - | - | - | - | - |
| Total | 5 | 70 | - | 75 | 5 | 78 | 1 | 84 | 6 | 71 | 1 | 78 | 5 | 84 | - | 89 | 5 | 64 | - | 69 |
| Week 20 | | | | | | | | | | | | | | | | | | | | |
| Low | 3 | 5 | - | 8 | 2 | - | - | 2 | 1 | 2 | - | 3 | 3 | 1 | - | 4 | 4 | - | - | 4 |
| Normal | 2 | 65 | - | 67 | 3 | 75 | - | 78 | 5 | 66 | - | 71 | 2 | 81 | - | 83 | 1 | 60 | - | 61 |
| High | - | - | - | - | - | - | 1 | 1 | - | 2 | 1 | 3 | - | - | - | - | - | - | - | - |
| Total | 5 | 70 | - | 75 | 5 | 75 | 1 | 81 | 6 | 70 | 1 | 77 | 5 | 82 | - | 87 | 5 | 60 | - | 65 |
| Week 24 | | | | | | | | | | | | | | | | | | | | |
| Low | 3 | 5 | - | 8 | 2 | - | - | 2 | 1 | 2 | - | 3 | 3 | 1 | - | 4 | 3 | - | - | 3 |
| Normal | 1 | 59 | - | 60 | 3 | 73 | 1 | 77 | 5 | 67 | - | 72 | 2 | 82 | - | 84 | 2 | 57 | - | 59 |
| High | - | - | - | - | - | - | - | - | - | - | 1 | 1 | - | - | - | - | - | - | - | - |
| Total | 4 | 64 | - | 68 | 5 | 73 | 1 | 79 | 6 | 69 | 1 | 76 | 5 | 83 | - | 88 | 5 | 57 | - | 62 |
| Follow-up | | | | | | | | | | | | | | | | | | | | |
| Low | 4 | 6 | - | 10 | 2 | - | - | 2 | 1 | 2 | - | 3 | 3 | 1 | - | 4 | 1 | - | - | 1 |
| Normal | 1 | 66 | - | 67 | 3 | 76 | 1 | 80 | 5 | 68 | - | 73 | 2 | 83 | - | 85 | 4 | 64 | - | 68 |
| High | - | - | - | - | - | 1 | - | 1 | - | - | 1 | 1 | - | - | - | - | - | - | - | - |
| Total | 5 | 72 | - | 77 | 5 | 77 | 1 | 83 | 6 | 70 | 1 | 77 | 5 | 84 | - | 89 | 5 | 64 | - | 69 |

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

## 表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Reticulocytes

| | Baseline | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Placebo (N=97) | | | | TAK-385 10mg (N=103) | | | | TAK-385 20mg (N=100) | | | | TAK-385 40mg (N=103) | | | | Leuprorelin (N=80) | | | |
| Visit | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total | Low | Normal | High | Total |
| Week 4 | | | | | | | | | | | | | | | | | | | | |
| Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Normal | - | 96 | 1 | 97 | - | 102 | - | 102 | - | 100 | - | 100 | - | 103 | - | 103 | - | 80 | - | 80 |
| High | - | - | - | - | - | 1 | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | - | 96 | 1 | 97 | - | 103 | - | 103 | - | 100 | - | 100 | - | 103 | - | 103 | - | 80 | - | 80 |
| Week 8 | | | | | | | | | | | | | | | | | | | | |
| Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Normal | - | 94 | 1 | 95 | - | 102 | - | 102 | - | 96 | - | 96 | - | 101 | - | 101 | - | 78 | - | 78 |
| High | - | - | - | - | - | 1 | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | - | 94 | 1 | 95 | - | 103 | - | 103 | - | 96 | - | 96 | - | 101 | - | 101 | - | 78 | - | 78 |
| Week 12 | | | | | | | | | | | | | | | | | | | | |
| Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Normal | - | 91 | 1 | 92 | - | 101 | - | 101 | - | 92 | - | 92 | - | 101 | - | 101 | - | 75 | - | 75 |
| High | - | 1 | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | - | 92 | 1 | 93 | - | 101 | - | 101 | - | 92 | - | 92 | - | 101 | - | 101 | - | 75 | - | 75 |
| Week 16 | | | | | | | | | | | | | | | | | | | | |
| Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Normal | - | 75 | - | 75 | - | 84 | - | 84 | - | 78 | - | 78 | - | 89 | - | 89 | - | 69 | - | 69 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | - | 75 | - | 75 | - | 84 | - | 84 | - | 78 | - | 78 | - | 89 | - | 89 | - | 69 | - | 69 |
| Week 20 | | | | | | | | | | | | | | | | | | | | |
| Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Normal | - | 75 | - | 75 | - | 81 | - | 81 | - | 77 | - | 77 | - | 87 | - | 87 | - | 65 | - | 65 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | - | 75 | - | 75 | - | 81 | - | 81 | - | 77 | - | 77 | - | 87 | - | 87 | - | 65 | - | 65 |
| Week 24 | | | | | | | | | | | | | | | | | | | | |
| Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Normal | - | 68 | - | 68 | - | 79 | - | 79 | - | 76 | - | 76 | - | 88 | - | 88 | - | 62 | - | 62 |
| High | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | - | 68 | - | 68 | - | 79 | - | 79 | - | 76 | - | 76 | - | 88 | - | 88 | - | 62 | - | 62 |
| Follow-up | | | | | | | | | | | | | | | | | | | | |
| Low | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Normal | - | 76 | - | 76 | - | 83 | - | 83 | - | 77 | - | 77 | - | 89 | - | 89 | - | 68 | - | 68 |
| High | - | 1 | - | 1 | - | - | - | - | - | - | - | - | - | - | - | - | - | 1 | - | 1 |
| Total | - | 77 | - | 77 | - | 83 | - | 83 | - | 77 | - | 77 | - | 89 | - | 89 | - | 69 | - | 69 |

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

## 表 2.7.4.8-付録-30　血液学的検査値の MAV の発現頻度（安全性データの解析対象集団）（CCT-002 試験）

| | Number of Subjects (%) | |
|---|---|---|
| | TAK-385 40mg (N=138) | Leuprorelin (N=142) |
| RBC | | |
| RBC Lower | 0/138( 0.0) | 0/142( 0.0) |
| RBC Upper | 0/138( 0.0) | 0/142( 0.0) |
| Platelets | | |
| Platelets Lower | 0/138( 0.0) | 0/142( 0.0) |
| Platelets Upper | 0/138( 0.0) | 0/142( 0.0) |
| WBC | | |
| WBC Lower | 0/138( 0.0) | 0/142( 0.0) |
| WBC Upper | 1/138( 0.7) | 0/142( 0.0) |
| Neutrophils | | |
| Neutrophils Lower | 0/138( 0.0) | 0/142( 0.0) |
| Neutrophils Upper | 0/138( 0.0) | 0/142( 0.0) |
| Eosinophils | | |
| Eosinophils Upper | 3/138( 2.2) | 4/142( 2.8) |
| Basophils | | |
| Basophils Upper | 0/138( 0.0) | 0/142( 0.0) |
| Lymphocytes | | |
| Lymphocytes Lower | 0/138( 0.0) | 0/142( 0.0) |
| Lymphocytes Upper | 0/138( 0.0) | 0/142( 0.0) |
| Monocytes | | |
| Monocytes Upper | 0/138( 0.0) | 0/142( 0.0) |

治験総括報告書 Table 15.3.2.1.4.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-31　血液学的検査値の MAV の発現頻度（安全性データの解析対象集団）（3008 試験）

| | Number of Subjects (%) | |
|---|---|---|
| | TAK-385 40mg (N=33) | Placebo (N=32) |
| RBC | | |
| RBC Lower | 0/33( 0.0) | 0/32( 0.0) |
| RBC Upper | 0/33( 0.0) | 0/32( 0.0) |
| Hemoglobin | | |
| Hemoglobin Lower | 0/33( 0.0) | 1/32( 3.1) |
| Hemoglobin Upper | 0/33( 0.0) | 0/32( 0.0) |
| Hematocrit | | |
| Hematocrit Lower | 0/33( 0.0) | 0/32( 0.0) |
| Hematocrit Upper | 0/33( 0.0) | 0/32( 0.0) |
| Platelets | | |
| Platelets Lower | 0/33( 0.0) | 0/32( 0.0) |
| Platelets Upper | 0/33( 0.0) | 0/32( 0.0) |
| WBC | | |
| WBC Lower | 0/33( 0.0) | 0/32( 0.0) |
| WBC Upper | 0/33( 0.0) | 1/32( 3.1) |
| Neutrophils | | |
| Neutrophils Lower | 0/33( 0.0) | 0/32( 0.0) |
| Neutrophils Upper | 0/33( 0.0) | 0/32( 0.0) |
| Eosinophils | | |
| Eosinophils Upper | 0/33( 0.0) | 0/32( 0.0) |
| Basophils | | |
| Basophils Upper | 0/33( 0.0) | 0/32( 0.0) |
| Lymphocytes | | |
| Lymphocytes Lower | 0/33( 0.0) | 0/32( 0.0) |
| Lymphocytes Upper | 0/33( 0.0) | 0/32( 0.0) |
| Monocytes | | |
| Monocytes Upper | 0/33( 0.0) | 0/32( 0.0) |

治験総括報告書 Table 15.3.2.1.4.1（5.3.5.1-3）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (GPT) (U/L)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 16.5 | | 15.7 | | 14.2 | | 14.8 | |
| SD | 8.24 | | 5.97 | | 4.64 | | 8.17 | |
| Minimum | 7 | | 7 | | 7 | | 8 | |
| Q1 | 11.0 | | 12.0 | | 11.0 | | 10.0 | |
| Median | 13.0 | | 13.0 | | 13.0 | | 12.5 | |
| Q3 | 19.0 | | 18.0 | | 17.0 | | 16.0 | |
| Maximum | 42 | | 35 | | 29 | | 59 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 16.1 | -0.4 | 17.1 | 1.4 | 15.9 | 1.7 | 16.4 | 1.6 |
| SD | 7.87 | 5.57 | 8.29 | 4.81 | 5.25 | 3.95 | 7.41 | 4.84 |
| Minimum | 7 | -24 | 8 | -9 | 8 | -10 | 8 | -21 |
| Q1 | 11.0 | -2.0 | 12.0 | -1.0 | 12.0 | 0.0 | 13.0 | 0.0 |
| Median | 13.0 | 0.0 | 14.5 | 0.0 | 16.0 | 2.0 | 14.5 | 1.0 |
| Q3 | 18.0 | 2.0 | 18.0 | 3.0 | 19.0 | 3.0 | 18.0 | 4.0 |
| Maximum | 58 | 18 | 42 | 16 | 36 | 13 | 43 | 16 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 16.4 | -0.2 | 19.1 | 3.4 | 16.5 | 2.3 | 18.4 | 3.6 |
| SD | 8.62 | 5.51 | 11.96 | 9.25 | 7.60 | 5.59 | 9.50 | 7.24 |
| Minimum | 6 | -14 | 7 | -11 | 8 | -6 | 7 | -21 |
| Q1 | 11.0 | -2.5 | 12.0 | -1.0 | 11.0 | -1.0 | 12.0 | 0.0 |
| Median | 13.0 | 0.0 | 14.5 | 1.0 | 14.0 | 1.0 | 15.0 | 2.0 |
| Q3 | 19.5 | 2.0 | 19.5 | 3.0 | 19.0 | 3.0 | 23.0 | 5.0 |
| Maximum | 52 | 15 | 58 | 36 | 48 | 25 | 58 | 26 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 17.9 | 1.2 | 17.1 | 1.6 | 17.0 | 2.8 | 18.8 | 4.0 |
| SD | 10.61 | 6.66 | 10.56 | 8.13 | 8.97 | 6.91 | 12.07 | 9.11 |
| Minimum | 9 | -15 | 6 | -15 | 8 | -7 | 7 | -16 |
| Q1 | 11.0 | -2.0 | 11.0 | -1.0 | 12.0 | 0.0 | 12.0 | -1.0 |
| Median | 13.0 | 0.0 | 14.0 | 0.0 | 14.0 | 1.0 | 14.5 | 2.0 |
| Q3 | 23.0 | 3.0 | 19.0 | 3.0 | 17.0 | 4.0 | 21.0 | 5.0 |
| Maximum | 68 | 28 | 62 | 34 | 55 | 32 | 67 | 41 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (GPT) (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 16.8 | 0.3 | 15.8 | 0.1 | 16.3 | 2.1 | 17.5 | 2.8 |
| SD | 10.75 | 7.36 | 9.24 | 7.28 | 10.83 | 9.96 | 8.73 | 7.95 |
| Minimum | 8 | -21 | 6 | -16 | 7 | -12 | 8 | -33 |
| Q1 | 11.0 | -2.0 | 11.0 | -3.5 | 11.0 | -2.0 | 12.0 | -1.0 |
| Median | 13.0 | 0.0 | 13.0 | 0.0 | 13.0 | 1.0 | 15.0 | 1.0 |
| Q3 | 20.0 | 2.0 | 17.0 | 2.0 | 19.0 | 3.0 | 21.0 | 5.0 |
| Maximum | 81 | 41 | 58 | 30 | 72 | 59 | 48 | 21 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (GOT) (U/L)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 17.7 | | 18.2 | | 17.8 | | 18.2 | |
| SD | 4.21 | | 3.73 | | 3.98 | | 4.94 | |
| Minimum | 12 | | 12 | | 12 | | 12 | |
| Q1 | 15.0 | | 16.0 | | 15.0 | | 15.0 | |
| Median | 17.0 | | 17.0 | | 17.0 | | 17.0 | |
| Q3 | 19.0 | | 19.5 | | 20.0 | | 21.0 | |
| Maximum | 34 | | 31 | | 30 | | 42 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 17.6 | 0.0 | 18.7 | 0.6 | 19.0 | 1.2 | 19.0 | 0.8 |
| SD | 4.31 | 4.08 | 3.39 | 3.16 | 4.08 | 3.45 | 3.96 | 3.39 |
| Minimum | 12 | -20 | 14 | -9 | 13 | -7 | 12 | -9 |
| Q1 | 15.0 | -2.0 | 16.0 | -1.0 | 16.0 | -1.0 | 17.0 | -1.0 |
| Median | 17.0 | 0.0 | 18.0 | 0.0 | 19.0 | 1.0 | 18.0 | 1.0 |
| Q3 | 19.0 | 1.0 | 21.0 | 2.0 | 22.0 | 3.0 | 20.0 | 3.0 |
| Maximum | 42 | 14 | 28 | 11 | 32 | 11 | 33 | 9 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 17.4 | -0.2 | 19.6 | 1.5 | 19.6 | 1.9 | 20.1 | 1.9 |
| SD | 3.82 | 3.76 | 5.32 | 5.02 | 5.54 | 4.26 | 4.96 | 4.25 |
| Minimum | 12 | -13 | 15 | -12 | 12 | -6 | 13 | -13 |
| Q1 | 15.0 | -2.0 | 16.5 | -1.0 | 16.0 | 0.0 | 16.0 | 0.0 |
| Median | 17.0 | 0.0 | 18.0 | 1.0 | 17.0 | 1.0 | 19.0 | 2.0 |
| Q3 | 18.5 | 1.0 | 20.0 | 3.0 | 23.0 | 3.0 | 23.0 | 4.0 |
| Maximum | 35 | 11 | 40 | 17 | 38 | 17 | 34 | 12 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 18.5 | 0.8 | 18.5 | 0.6 | 19.4 | 1.7 | 20.5 | 2.3 |
| SD | 6.02 | 5.34 | 4.22 | 4.27 | 5.92 | 5.03 | 6.47 | 5.22 |
| Minimum | 12 | -12 | 12 | -11 | 12 | -7 | 12 | -8 |
| Q1 | 15.0 | -1.0 | 16.0 | -1.0 | 16.0 | -1.0 | 17.0 | 0.0 |
| Median | 17.0 | 0.0 | 17.0 | 0.0 | 17.0 | 1.0 | 19.0 | 2.0 |
| Q3 | 21.0 | 2.0 | 20.0 | 2.0 | 21.0 | 3.0 | 22.0 | 3.0 |
| Maximum | 50 | 22 | 37 | 16 | 36 | 17 | 44 | 27 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (GOT) (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 17.8 | 0.1 | 17.6 | -0.6 | 18.3 | 0.5 | 19.5 | 1.3 |
| SD | 5.15 | 4.42 | 4.02 | 4.59 | 6.82 | 6.78 | 4.91 | 5.26 |
| Minimum | 11 | -18 | 14 | -15 | 11 | -11 | 13 | -21 |
| Q1 | 15.0 | -1.0 | 15.0 | -2.0 | 15.0 | -2.0 | 16.0 | -1.0 |
| Median | 17.0 | 0.0 | 17.0 | -1.0 | 16.0 | 0.0 | 18.5 | 1.0 |
| Q3 | 19.0 | 2.0 | 19.0 | 2.0 | 20.0 | 1.0 | 22.0 | 4.0 |
| Maximum | 49 | 21 | 34 | 13 | 51 | 35 | 37 | 17 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDH (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 163.4 | | 161.0 | | 164.3 | | 168.4 | |
| SD | 33.94 | | 20.08 | | 36.81 | | 27.34 | |
| Minimum | 113 | | 119 | | 121 | | 106 | |
| Q1 | 141.0 | | 147.0 | | 141.0 | | 153.0 | |
| Median | 161.0 | | 160.5 | | 157.0 | | 163.0 | |
| Q3 | 178.0 | | 174.0 | | 180.0 | | 182.0 | |
| Maximum | 324 | | 217 | | 348 | | 244 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 161.5 | -1.9 | 166.3 | 5.2 | 168.5 | 4.2 | 172.4 | 4.0 |
| SD | 34.79 | 16.13 | 26.84 | 18.02 | 29.11 | 28.30 | 24.22 | 23.19 |
| Minimum | 120 | -45 | 104 | -33 | 113 | -146 | 123 | -78 |
| Q1 | 142.0 | -13.0 | 148.0 | -5.0 | 149.0 | -2.0 | 156.0 | -5.0 |
| Median | 153.0 | 1.0 | 158.5 | 2.5 | 167.0 | 6.0 | 172.5 | 5.5 |
| Q3 | 172.0 | 8.0 | 190.5 | 15.5 | 184.0 | 17.0 | 181.0 | 19.0 |
| Maximum | 358 | 34 | 235 | 64 | 238 | 52 | 236 | 51 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 161.0 | -2.7 | 168.0 | 7.0 | 166.6 | 3.7 | 171.9 | 3.5 |
| SD | 45.07 | 23.65 | 36.40 | 32.97 | 28.71 | 27.07 | 23.58 | 20.96 |
| Minimum | 104 | -66 | 107 | -31 | 121 | -159 | 132 | -72 |
| Q1 | 140.0 | -15.0 | 153.0 | -9.5 | 145.0 | -1.0 | 154.0 | -3.0 |
| Median | 149.5 | -1.0 | 163.0 | 0.5 | 167.5 | 9.0 | 171.5 | 3.0 |
| Q3 | 179.0 | 5.0 | 180.0 | 17.0 | 185.0 | 14.0 | 185.0 | 16.0 |
| Maximum | 440 | 116 | 357 | 200 | 252 | 45 | 242 | 41 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 162.4 | -1.5 | 167.0 | 5.2 | 168.5 | 5.1 | 176.0 | 7.6 |
| SD | 31.12 | 23.40 | 22.60 | 15.58 | 27.60 | 29.28 | 25.61 | 19.11 |
| Minimum | 109 | -66 | 124 | -37 | 129 | -160 | 120 | -67 |
| Q1 | 138.0 | -14.0 | 148.0 | -6.0 | 149.0 | -1.0 | 161.0 | 1.0 |
| Median | 156.0 | -5.0 | 168.0 | 5.0 | 164.0 | 9.0 | 174.5 | 11.0 |
| Q3 | 186.0 | 12.0 | 185.0 | 19.0 | 182.0 | 18.0 | 187.0 | 18.0 |
| Maximum | 285 | 70 | 211 | 32 | 243 | 46 | 250 | 41 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDH (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 160.8 | -2.6 | 164.3 | 3.3 | 164.7 | 0.4 | 170.8 | 2.4 |
| SD | 27.53 | 16.50 | 29.41 | 24.81 | 45.45 | 51.48 | 34.41 | 27.54 |
| Minimum | 115 | -55 | 105 | -36 | 112 | -201 | 115 | -69 |
| Q1 | 144.0 | -13.0 | 148.0 | -11.5 | 142.0 | -11.0 | 148.0 | -9.0 |
| Median | 158.0 | 1.0 | 163.5 | 1.5 | 157.0 | 0.0 | 166.0 | 0.5 |
| Q3 | 172.0 | 8.0 | 178.5 | 10.5 | 176.0 | 10.0 | 179.0 | 11.0 |
| Maximum | 284 | 28 | 311 | 126 | 440 | 292 | 345 | 129 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: GGT (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 21.6 | | 20.3 | | 17.7 | | 20.9 | |
| SD | 17.48 | | 13.24 | | 8.00 | | 24.38 | |
| Minimum | 7 | | 9 | | 9 | | 8 | |
| Q1 | 12.0 | | 12.0 | | 12.0 | | 12.0 | |
| Median | 15.0 | | 15.5 | | 15.0 | | 14.5 | |
| Q3 | 21.0 | | 21.5 | | 21.0 | | 21.0 | |
| Maximum | 93 | | 76 | | 43 | | 171 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 20.5 | -1.1 | 22.1 | 1.8 | 18.6 | 0.9 | 22.7 | 1.8 |
| SD | 13.36 | 6.40 | 15.30 | 6.40 | 8.42 | 2.75 | 22.72 | 4.02 |
| Minimum | 9 | -33 | 8 | -12 | 8 | -10 | 8 | -16 |
| Q1 | 13.0 | -1.0 | 14.0 | -1.0 | 13.0 | 0.0 | 14.0 | 0.0 |
| Median | 16.0 | 0.0 | 15.5 | 1.0 | 16.0 | 1.0 | 17.0 | 2.0 |
| Q3 | 22.0 | 1.0 | 22.0 | 3.0 | 22.0 | 2.0 | 23.0 | 3.0 |
| Maximum | 68 | 6 | 70 | 25 | 50 | 9 | 155 | 14 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 21.0 | -0.8 | 23.4 | 3.0 | 19.7 | 1.9 | 24.5 | 3.6 |
| SD | 14.04 | 7.36 | 21.02 | 9.19 | 10.04 | 4.91 | 27.39 | 6.08 |
| Minimum | 9 | -31 | 9 | -7 | 7 | -11 | 8 | -7 |
| Q1 | 13.0 | -1.5 | 13.0 | -1.0 | 13.0 | -1.0 | 14.0 | 0.0 |
| Median | 15.5 | 0.0 | 15.5 | 0.5 | 16.0 | 1.0 | 18.0 | 2.0 |
| Q3 | 20.5 | 1.0 | 24.0 | 3.0 | 23.0 | 3.0 | 24.0 | 5.0 |
| Maximum | 66 | 22 | 125 | 49 | 55 | 18 | 194 | 23 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 20.7 | -1.0 | 22.2 | 1.7 | 19.5 | 1.7 | 23.7 | 2.8 |
| SD | 13.99 | 8.27 | 15.04 | 7.71 | 10.01 | 5.48 | 21.50 | 9.09 |
| Minimum | 7 | -38 | 9 | -15 | 8 | -11 | 9 | -40 |
| Q1 | 12.0 | -2.0 | 14.0 | -1.0 | 13.0 | -1.0 | 13.0 | 0.0 |
| Median | 15.0 | 0.0 | 17.0 | 1.0 | 16.0 | 1.0 | 16.5 | 2.0 |
| Q3 | 22.0 | 2.0 | 24.0 | 3.0 | 22.0 | 4.0 | 24.0 | 4.0 |
| Maximum | 80 | 18 | 78 | 36 | 54 | 26 | 131 | 36 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: GGT (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 20.5 | -1.1 | 20.3 | 0.0 | 19.0 | 1.3 | 21.0 | 0.1 |
| SD | 13.70 | 6.87 | 14.91 | 8.34 | 11.34 | 6.82 | 18.92 | 9.57 |
| Minimum | 7 | -29 | 8 | -19 | 8 | -11 | 7 | -59 |
| Q1 | 12.0 | -1.0 | 12.0 | -2.0 | 12.0 | -2.0 | 12.0 | -2.0 |
| Median | 15.0 | 0.0 | 17.0 | -1.0 | 14.0 | 0.0 | 16.0 | 0.0 |
| Q3 | 25.0 | 1.0 | 20.0 | 2.0 | 20.0 | 2.0 | 20.0 | 2.0 |
| Maximum | 68 | 9 | 79 | 36 | 62 | 34 | 112 | 27 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 4.22 | | 4.25 | | 4.23 | | 4.25 | |
| SD | 0.235 | | 0.226 | | 0.209 | | 0.201 | |
| Minimum | 3.8 | | 3.8 | | 3.7 | | 3.7 | |
| Q1 | 4.10 | | 4.10 | | 4.10 | | 4.10 | |
| Median | 4.20 | | 4.20 | | 4.20 | | 4.20 | |
| Q3 | 4.30 | | 4.40 | | 4.40 | | 4.40 | |
| Maximum | 4.8 | | 4.8 | | 4.7 | | 4.9 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 4.18 | -0.04 | 4.27 | 0.02 | 4.38 | 0.14 | 4.40 | 0.16 |
| SD | 0.209 | 0.216 | 0.230 | 0.258 | 0.193 | 0.179 | 0.196 | 0.224 |
| Minimum | 3.7 | -0.6 | 3.8 | -0.6 | 4.1 | -0.3 | 4.0 | -0.4 |
| Q1 | 4.10 | -0.20 | 4.10 | -0.20 | 4.20 | 0.00 | 4.20 | 0.00 |
| Median | 4.10 | 0.00 | 4.20 | 0.00 | 4.30 | 0.10 | 4.40 | 0.20 |
| Q3 | 4.30 | 0.10 | 4.50 | 0.20 | 4.50 | 0.30 | 4.60 | 0.30 |
| Maximum | 5.0 | 0.4 | 4.7 | 0.5 | 4.9 | 0.6 | 4.8 | 0.6 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 4.20 | -0.03 | 4.29 | 0.04 | 4.38 | 0.14 | 4.40 | 0.15 |
| SD | 0.230 | 0.191 | 0.260 | 0.245 | 0.224 | 0.185 | 0.189 | 0.214 |
| Minimum | 3.9 | -0.4 | 3.6 | -0.4 | 3.9 | -0.3 | 3.9 | -0.6 |
| Q1 | 4.00 | -0.10 | 4.10 | -0.15 | 4.20 | 0.00 | 4.30 | 0.00 |
| Median | 4.10 | 0.00 | 4.30 | 0.00 | 4.40 | 0.10 | 4.40 | 0.15 |
| Q3 | 4.30 | 0.10 | 4.40 | 0.20 | 4.50 | 0.20 | 4.50 | 0.30 |
| Maximum | 4.9 | 0.5 | 4.9 | 0.7 | 4.9 | 0.6 | 5.0 | 0.6 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 46 | 46 | 53 | 53 | 54 | 54 |
| Mean | 4.23 | 0.00 | 4.31 | 0.05 | 4.36 | 0.12 | 4.39 | 0.14 |
| SD | 0.215 | 0.228 | 0.209 | 0.180 | 0.205 | 0.201 | 0.177 | 0.212 |
| Minimum | 3.7 | -0.6 | 3.8 | -0.3 | 4.0 | -0.3 | 4.0 | -0.4 |
| Q1 | 4.10 | -0.20 | 4.20 | -0.10 | 4.20 | 0.00 | 4.30 | 0.00 |
| Median | 4.20 | 0.00 | 4.35 | 0.05 | 4.40 | 0.10 | 4.40 | 0.10 |
| Q3 | 4.40 | 0.10 | 4.40 | 0.20 | 4.50 | 0.30 | 4.50 | 0.30 |
| Maximum | 4.8 | 0.5 | 4.8 | 0.4 | 4.8 | 0.5 | 4.8 | 0.6 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 4.18 | -0.04 | 4.17 | -0.08 | 4.20 | -0.03 | 4.21 | -0.04 |
| SD | 0.232 | 0.187 | 0.233 | 0.212 | 0.204 | 0.201 | 0.203 | 0.217 |
| Minimum | 3.8 | -0.6 | 3.6 | -0.5 | 3.7 | -0.5 | 3.7 | -0.7 |
| Q1 | 4.00 | -0.20 | 4.00 | -0.20 | 4.10 | -0.20 | 4.10 | -0.20 |
| Median | 4.20 | 0.00 | 4.20 | -0.10 | 4.20 | 0.00 | 4.20 | 0.00 |
| Q3 | 4.30 | 0.10 | 4.30 | 0.10 | 4.40 | 0.10 | 4.40 | 0.10 |
| Maximum | 4.8 | 0.4 | 4.7 | 0.5 | 4.6 | 0.3 | 4.7 | 0.4 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline Phosphatase (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 172.6 | | 169.0 | | 169.7 | | 178.9 | |
| SD | 45.79 | | 47.83 | | 50.35 | | 54.16 | |
| Minimum | 85 | | 86 | | 60 | | 94 | |
| Q1 | 140.0 | | 130.0 | | 133.0 | | 144.0 | |
| Median | 160.0 | | 168.5 | | 169.0 | | 170.0 | |
| Q3 | 207.0 | | 192.0 | | 196.0 | | 203.0 | |
| Maximum | 314 | | 326 | | 378 | | 378 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 167.0 | -5.6 | 176.6 | 7.6 | 176.2 | 6.5 | 182.9 | 4.1 |
| SD | 42.25 | 18.91 | 48.20 | 23.04 | 45.57 | 20.77 | 55.23 | 22.97 |
| Minimum | 88 | -78 | 87 | -44 | 62 | -63 | 106 | -53 |
| Q1 | 133.0 | -12.0 | 139.0 | -5.0 | 137.0 | -6.0 | 145.0 | -9.0 |
| Median | 165.0 | -3.0 | 172.0 | 7.0 | 169.0 | 5.0 | 177.0 | 7.0 |
| Q3 | 187.0 | 4.0 | 205.0 | 18.0 | 214.0 | 19.0 | 217.0 | 15.0 |
| Maximum | 269 | 26 | 345 | 78 | 315 | 59 | 383 | 63 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 172.1 | -0.5 | 176.2 | 7.2 | 178.6 | 8.0 | 194.3 | 15.4 |
| SD | 44.86 | 21.73 | 53.31 | 22.13 | 45.48 | 20.05 | 80.25 | 48.63 |
| Minimum | 84 | -73 | 82 | -41 | 62 | -50 | 101 | -88 |
| Q1 | 140.0 | -9.5 | 140.0 | -9.0 | 148.0 | -6.0 | 150.0 | 3.0 |
| Median | 162.5 | 1.5 | 171.0 | 6.0 | 171.0 | 7.5 | 180.5 | 8.5 |
| Q3 | 199.0 | 10.5 | 203.5 | 18.0 | 205.0 | 18.0 | 220.0 | 25.0 |
| Maximum | 305 | 59 | 393 | 67 | 328 | 67 | 638 | 313 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 173.2 | -0.4 | 173.3 | 7.7 | 185.1 | 14.7 | 196.4 | 17.5 |
| SD | 44.00 | 19.57 | 45.06 | 17.22 | 44.05 | 28.58 | 59.51 | 27.56 |
| Minimum | 86 | -75 | 73 | -35 | 78 | -120 | 119 | -86 |
| Q1 | 142.0 | -8.0 | 143.0 | -6.0 | 155.0 | -1.0 | 154.0 | 6.0 |
| Median | 163.0 | 0.0 | 168.0 | 9.0 | 183.0 | 17.0 | 189.5 | 20.0 |
| Q3 | 213.0 | 9.0 | 192.0 | 22.0 | 211.0 | 29.0 | 220.0 | 30.0 |
| Maximum | 270 | 67 | 307 | 50 | 289 | 68 | 458 | 101 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline Phosphatase (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 174.7 | 2.1 | 173.5 | 4.5 | 181.8 | 12.1 | 190.7 | 11.8 |
| SD | 54.01 | 32.82 | 48.91 | 23.75 | 47.55 | 32.31 | 52.24 | 27.54 |
| Minimum | 98 | -50 | 85 | -48 | 65 | -136 | 112 | -95 |
| Q1 | 144.0 | -12.0 | 137.5 | -7.5 | 155.0 | -3.0 | 152.0 | 3.0 |
| Median | 160.0 | 1.0 | 171.5 | 3.0 | 186.0 | 8.0 | 184.5 | 15.0 |
| Q3 | 201.0 | 13.0 | 199.0 | 15.0 | 212.0 | 38.0 | 214.0 | 25.0 |
| Maximum | 405 | 199 | 353 | 80 | 315 | 69 | 359 | 66 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Bilirubin (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 0.44 | | 0.46 | | 0.46 | | 0.48 | |
| SD | 0.179 | | 0.208 | | 0.167 | | 0.211 | |
| Minimum | 0.1 | | 0.2 | | 0.2 | | 0.2 | |
| Q1 | 0.30 | | 0.35 | | 0.30 | | 0.30 | |
| Median | 0.40 | | 0.40 | | 0.40 | | 0.40 | |
| Q3 | 0.60 | | 0.50 | | 0.60 | | 0.60 | |
| Maximum | 0.9 | | 1.2 | | 0.9 | | 1.4 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 0.46 | 0.01 | 0.49 | 0.03 | 0.49 | 0.03 | 0.52 | 0.04 |
| SD | 0.164 | 0.113 | 0.207 | 0.128 | 0.203 | 0.182 | 0.214 | 0.150 |
| Minimum | 0.1 | -0.3 | 0.2 | -0.3 | 0.2 | -0.4 | 0.2 | -0.2 |
| Q1 | 0.40 | -0.10 | 0.30 | 0.00 | 0.40 | -0.10 | 0.40 | -0.10 |
| Median | 0.40 | 0.00 | 0.45 | 0.00 | 0.50 | 0.00 | 0.50 | 0.00 |
| Q3 | 0.50 | 0.10 | 0.60 | 0.10 | 0.60 | 0.20 | 0.60 | 0.20 |
| Maximum | 1.0 | 0.3 | 1.2 | 0.3 | 1.5 | 0.7 | 1.3 | 0.4 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 0.48 | 0.03 | 0.49 | 0.02 | 0.54 | 0.08 | 0.55 | 0.07 |
| SD | 0.194 | 0.193 | 0.169 | 0.134 | 0.228 | 0.203 | 0.258 | 0.160 |
| Minimum | 0.2 | -0.5 | 0.2 | -0.4 | 0.2 | -0.4 | 0.2 | -0.2 |
| Q1 | 0.35 | -0.05 | 0.40 | 0.00 | 0.40 | 0.00 | 0.40 | 0.00 |
| Median | 0.50 | 0.00 | 0.40 | 0.00 | 0.50 | 0.10 | 0.50 | 0.10 |
| Q3 | 0.60 | 0.20 | 0.60 | 0.10 | 0.60 | 0.20 | 0.60 | 0.20 |
| Maximum | 1.1 | 0.5 | 1.0 | 0.3 | 1.2 | 0.7 | 1.7 | 0.4 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 0.47 | 0.02 | 0.52 | 0.06 | 0.58 | 0.13 | 0.57 | 0.09 |
| SD | 0.164 | 0.129 | 0.238 | 0.158 | 0.205 | 0.199 | 0.238 | 0.211 |
| Minimum | 0.1 | -0.3 | 0.3 | -0.4 | 0.3 | -0.3 | 0.3 | -0.3 |
| Q1 | 0.40 | -0.10 | 0.40 | 0.00 | 0.40 | 0.00 | 0.40 | 0.00 |
| Median | 0.50 | 0.00 | 0.50 | 0.10 | 0.60 | 0.10 | 0.50 | 0.00 |
| Q3 | 0.60 | 0.10 | 0.60 | 0.20 | 0.70 | 0.20 | 0.70 | 0.20 |
| Maximum | 1.2 | 0.3 | 1.5 | 0.3 | 1.1 | 0.6 | 1.2 | 0.7 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Bilirubin (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 0.49 | 0.04 | 0.49 | 0.03 | 0.54 | 0.08 | 0.57 | 0.09 |
| SD | 0.163 | 0.139 | 0.137 | 0.173 | 0.208 | 0.216 | 0.246 | 0.218 |
| Minimum | 0.2 | -0.3 | 0.2 | -0.5 | 0.3 | -0.5 | 0.2 | -0.3 |
| Q1 | 0.40 | 0.00 | 0.40 | -0.10 | 0.40 | -0.10 | 0.40 | 0.00 |
| Median | 0.50 | 0.10 | 0.50 | 0.05 | 0.50 | 0.10 | 0.50 | 0.00 |
| Q3 | 0.60 | 0.10 | 0.60 | 0.20 | 0.70 | 0.20 | 0.70 | 0.20 |
| Maximum | 0.8 | 0.3 | 0.9 | 0.3 | 1.1 | 0.6 | 1.4 | 0.7 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Protein (g/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 7.03 | | 7.14 | | 7.02 | | 7.06 | |
| SD | 0.405 | | 0.417 | | 0.403 | | 0.406 | |
| Minimum | 6.2 | | 6.1 | | 6.2 | | 6.3 | |
| Q1 | 6.80 | | 6.90 | | 6.70 | | 6.80 | |
| Median | 7.00 | | 7.10 | | 7.00 | | 7.00 | |
| Q3 | 7.30 | | 7.35 | | 7.30 | | 7.30 | |
| Maximum | 8.0 | | 8.2 | | 7.9 | | 8.3 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 7.00 | -0.04 | 7.20 | 0.07 | 7.26 | 0.24 | 7.28 | 0.22 |
| SD | 0.394 | 0.372 | 0.370 | 0.378 | 0.405 | 0.345 | 0.392 | 0.363 |
| Minimum | 6.2 | -1.1 | 6.6 | -0.6 | 6.5 | -0.7 | 6.6 | -0.7 |
| Q1 | 6.80 | -0.30 | 6.90 | -0.30 | 7.00 | 0.00 | 7.00 | 0.00 |
| Median | 7.00 | 0.00 | 7.20 | 0.10 | 7.20 | 0.20 | 7.30 | 0.30 |
| Q3 | 7.20 | 0.20 | 7.40 | 0.40 | 7.60 | 0.50 | 7.50 | 0.50 |
| Maximum | 8.4 | 0.8 | 8.1 | 0.8 | 8.7 | 1.2 | 8.3 | 0.8 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 7.00 | -0.04 | 7.19 | 0.06 | 7.25 | 0.23 | 7.31 | 0.25 |
| SD | 0.421 | 0.361 | 0.404 | 0.422 | 0.460 | 0.342 | 0.385 | 0.368 |
| Minimum | 6.2 | -1.0 | 6.5 | -0.7 | 6.3 | -0.7 | 6.4 | -0.9 |
| Q1 | 6.70 | -0.30 | 6.90 | -0.25 | 7.00 | 0.00 | 7.00 | 0.00 |
| Median | 6.95 | -0.10 | 7.20 | 0.10 | 7.10 | 0.20 | 7.30 | 0.20 |
| Q3 | 7.20 | 0.25 | 7.50 | 0.30 | 7.60 | 0.50 | 7.50 | 0.50 |
| Maximum | 8.4 | 0.8 | 8.0 | 1.1 | 8.4 | 0.9 | 8.3 | 1.1 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 46 | 46 | 53 | 53 | 54 | 54 |
| Mean | 7.05 | 0.01 | 7.18 | 0.05 | 7.23 | 0.19 | 7.28 | 0.22 |
| SD | 0.406 | 0.397 | 0.373 | 0.322 | 0.460 | 0.374 | 0.343 | 0.360 |
| Minimum | 6.3 | -1.4 | 6.5 | -0.6 | 6.2 | -0.6 | 6.5 | -0.7 |
| Q1 | 6.80 | -0.20 | 7.00 | -0.20 | 6.90 | 0.00 | 7.00 | 0.00 |
| Median | 7.10 | 0.00 | 7.15 | 0.10 | 7.20 | 0.20 | 7.35 | 0.20 |
| Q3 | 7.30 | 0.20 | 7.40 | 0.30 | 7.60 | 0.40 | 7.50 | 0.40 |
| Maximum | 8.0 | 0.9 | 8.4 | 0.6 | 8.6 | 1.0 | 8.0 | 1.1 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Protein (g/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 6.97 | -0.06 | 6.96 | -0.18 | 6.94 | -0.08 | 6.96 | -0.10 |
| SD | 0.430 | 0.356 | 0.372 | 0.338 | 0.420 | 0.377 | 0.365 | 0.379 |
| Minimum | 6.2 | -1.3 | 6.1 | -0.8 | 5.9 | -1.2 | 5.8 | -1.3 |
| Q1 | 6.60 | -0.20 | 6.70 | -0.40 | 6.70 | -0.30 | 6.70 | -0.30 |
| Median | 6.90 | -0.10 | 6.90 | -0.20 | 6.90 | -0.10 | 6.90 | -0.10 |
| Q3 | 7.20 | 0.10 | 7.10 | 0.00 | 7.20 | 0.10 | 7.20 | 0.10 |
| Maximum | 8.2 | 0.7 | 8.3 | 0.9 | 8.2 | 0.6 | 7.9 | 0.8 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Cholesterol (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 189.7 | | 202.0 | | 194.3 | | 190.2 | |
| SD | 26.54 | | 27.50 | | 24.66 | | 32.17 | |
| Minimum | 125 | | 142 | | 154 | | 143 | |
| Q1 | 169.0 | | 182.5 | | 177.0 | | 168.0 | |
| Median | 188.0 | | 200.5 | | 193.0 | | 185.5 | |
| Q3 | 206.0 | | 221.0 | | 212.0 | | 211.0 | |
| Maximum | 261 | | 263 | | 244 | | 288 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 191.0 | 1.3 | 207.6 | 5.6 | 208.1 | 13.8 | 206.0 | 15.8 |
| SD | 25.93 | 21.58 | 29.07 | 19.55 | 29.67 | 20.40 | 33.25 | 17.44 |
| Minimum | 132 | -53 | 125 | -43 | 150 | -41 | 156 | -16 |
| Q1 | 175.0 | -10.0 | 192.5 | -5.0 | 182.0 | -4.0 | 180.0 | 3.0 |
| Median | 192.0 | -2.0 | 204.5 | 4.5 | 211.0 | 11.0 | 200.5 | 12.0 |
| Q3 | 209.0 | 15.0 | 228.5 | 18.0 | 230.0 | 33.0 | 228.0 | 28.0 |
| Maximum | 247 | 62 | 269 | 47 | 267 | 63 | 277 | 53 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 193.1 | 2.3 | 208.9 | 6.9 | 210.4 | 16.8 | 206.3 | 16.1 |
| SD | 27.65 | 25.05 | 27.67 | 21.75 | 28.96 | 23.29 | 31.79 | 21.25 |
| Minimum | 134 | -64 | 138 | -43 | 163 | -48 | 162 | -35 |
| Q1 | 172.5 | -15.5 | 191.5 | -6.5 | 189.0 | 5.0 | 183.0 | 5.0 |
| Median | 194.0 | 1.5 | 209.0 | 3.5 | 205.5 | 13.0 | 197.5 | 16.0 |
| Q3 | 211.5 | 23.0 | 227.5 | 24.5 | 233.0 | 32.0 | 239.0 | 31.0 |
| Maximum | 246 | 57 | 279 | 58 | 271 | 71 | 293 | 76 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 193.3 | 2.4 | 208.2 | 5.4 | 207.9 | 13.6 | 201.9 | 11.7 |
| SD | 22.83 | 24.30 | 27.02 | 22.12 | 28.05 | 24.79 | 35.40 | 23.07 |
| Minimum | 138 | -67 | 135 | -59 | 160 | -49 | 138 | -55 |
| Q1 | 178.0 | -12.0 | 196.0 | -10.0 | 187.0 | -1.0 | 178.0 | -5.0 |
| Median | 193.0 | 1.0 | 203.0 | 2.0 | 207.0 | 12.0 | 197.5 | 12.0 |
| Q3 | 206.0 | 17.0 | 223.0 | 21.0 | 223.0 | 27.0 | 220.0 | 26.0 |
| Maximum | 253 | 56 | 264 | 58 | 289 | 68 | 298 | 66 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Cholesterol (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 189.6 | -0.1 | 192.8 | -9.1 | 191.7 | -2.6 | 189.1 | -1.1 |
| SD | 23.53 | 20.02 | 28.97 | 22.11 | 26.02 | 21.70 | 28.55 | 21.60 |
| Minimum | 143 | -62 | 119 | -63 | 127 | -47 | 133 | -60 |
| Q1 | 172.0 | -16.0 | 174.0 | -23.5 | 173.0 | -20.0 | 169.0 | -15.0 |
| Median | 185.0 | 0.0 | 191.0 | -9.5 | 195.0 | -7.0 | 182.0 | -3.5 |
| Q3 | 205.0 | 15.0 | 207.0 | 4.0 | 209.0 | 10.0 | 206.0 | 11.0 |
| Maximum | 257 | 32 | 267 | 47 | 255 | 50 | 260 | 55 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HDL Cholesterol (mg/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 59.4 | | 66.1 | | 65.3 | | 63.6 | |
| SD | 12.58 | | 15.53 | | 12.47 | | 13.19 | |
| Minimum | 37 | | 28 | | 40 | | 35 | |
| Q1 | 51.0 | | 55.0 | | 55.0 | | 57.0 | |
| Median | 57.0 | | 65.0 | | 63.0 | | 63.5 | |
| Q3 | 67.0 | | 77.0 | | 75.0 | | 69.0 | |
| Maximum | 89 | | 106 | | 95 | | 107 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 60.2 | 0.8 | 67.9 | 1.8 | 68.8 | 3.5 | 68.1 | 4.5 |
| SD | 11.90 | 7.24 | 16.77 | 10.86 | 12.58 | 6.93 | 13.49 | 7.86 |
| Minimum | 37 | -14 | 36 | -26 | 44 | -12 | 34 | -22 |
| Q1 | 50.0 | -3.0 | 55.5 | -4.0 | 58.0 | -1.0 | 59.0 | 0.0 |
| Median | 58.0 | 0.0 | 65.5 | 1.0 | 70.0 | 4.0 | 68.5 | 4.0 |
| Q3 | 67.0 | 5.0 | 77.0 | 8.0 | 78.0 | 9.0 | 76.0 | 10.0 |
| Maximum | 89 | 21 | 115 | 29 | 97 | 16 | 109 | 25 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 60.4 | 0.8 | 67.5 | 1.4 | 69.0 | 3.8 | 67.6 | 4.0 |
| SD | 12.03 | 7.66 | 14.84 | 9.35 | 13.51 | 7.00 | 14.14 | 7.42 |
| Minimum | 39 | -16 | 41 | -17 | 43 | -13 | 32 | -14 |
| Q1 | 49.5 | -5.0 | 57.0 | -5.0 | 58.0 | 0.0 | 58.0 | -1.0 |
| Median | 60.5 | 1.0 | 66.0 | 1.0 | 67.0 | 4.0 | 68.0 | 4.0 |
| Q3 | 66.5 | 6.0 | 76.5 | 6.5 | 79.0 | 8.0 | 78.0 | 11.0 |
| Maximum | 94 | 18 | 110 | 24 | 95 | 18 | 98 | 17 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 61.1 | 1.7 | 67.1 | 1.5 | 67.6 | 2.6 | 67.1 | 3.5 |
| SD | 11.85 | 7.30 | 16.35 | 10.49 | 13.13 | 7.51 | 14.33 | 7.84 |
| Minimum | 38 | -11 | 34 | -19 | 42 | -14 | 33 | -14 |
| Q1 | 53.0 | -4.0 | 56.0 | -5.0 | 58.0 | -2.0 | 57.0 | -1.0 |
| Median | 61.0 | 1.0 | 66.0 | 2.0 | 66.0 | 3.0 | 65.5 | 4.5 |
| Q3 | 69.0 | 6.0 | 78.0 | 6.0 | 75.0 | 7.0 | 77.0 | 8.0 |
| Maximum | 89 | 25 | 120 | 34 | 94 | 22 | 97 | 25 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HDL Cholesterol (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 60.1 | 0.7 | 63.7 | -2.4 | 63.0 | -2.3 | 63.1 | -0.5 |
| SD | 12.03 | 7.83 | 16.55 | 10.23 | 12.35 | 7.29 | 13.38 | 7.46 |
| Minimum | 34 | -14 | 35 | -23 | 37 | -22 | 33 | -16 |
| Q1 | 53.0 | -5.0 | 50.0 | -10.0 | 53.0 | -7.0 | 55.0 | -6.0 |
| Median | 59.0 | -1.0 | 64.0 | -3.0 | 61.0 | -3.0 | 63.0 | -1.0 |
| Q3 | 69.0 | 6.0 | 74.0 | 5.5 | 73.0 | 1.0 | 70.0 | 5.0 |
| Maximum | 88 | 26 | 104 | 24 | 89 | 20 | 101 | 20 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDL Cholesterol (mg/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 111.4 | | 115.6 | | 111.5 | | 108.4 | |
| SD | 21.97 | | 24.23 | | 25.77 | | 28.41 | |
| Minimum | 49 | | 51 | | 64 | | 38 | |
| Q1 | 99.0 | | 102.0 | | 90.0 | | 94.0 | |
| Median | 107.0 | | 116.5 | | 110.0 | | 108.0 | |
| Q3 | 128.0 | | 133.0 | | 130.0 | | 126.0 | |
| Maximum | 172 | | 167 | | 177 | | 185 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 112.8 | 1.3 | 119.3 | 3.7 | 119.6 | 8.1 | 117.9 | 9.5 |
| SD | 21.71 | 15.53 | 26.88 | 13.79 | 29.26 | 16.01 | 26.74 | 14.54 |
| Minimum | 55 | -35 | 47 | -39 | 62 | -34 | 70 | -17 |
| Q1 | 96.0 | -8.0 | 102.0 | -3.5 | 103.0 | -4.0 | 101.0 | -3.0 |
| Median | 111.0 | 1.0 | 121.0 | 4.0 | 117.0 | 10.0 | 117.5 | 9.0 |
| Q3 | 125.0 | 9.0 | 138.0 | 11.5 | 140.0 | 18.0 | 133.0 | 18.0 |
| Maximum | 164 | 46 | 169 | 33 | 196 | 41 | 177 | 55 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 113.9 | 1.4 | 120.1 | 4.4 | 121.2 | 10.2 | 117.1 | 8.7 |
| SD | 22.77 | 19.02 | 26.44 | 15.23 | 30.33 | 18.60 | 27.70 | 17.28 |
| Minimum | 66 | -57 | 43 | -25 | 63 | -40 | 66 | -30 |
| Q1 | 97.5 | -12.5 | 110.0 | -5.5 | 100.0 | 0.0 | 95.0 | -3.0 |
| Median | 109.5 | -1.0 | 124.0 | 2.0 | 120.0 | 9.0 | 114.5 | 10.5 |
| Q3 | 131.5 | 18.0 | 137.5 | 15.0 | 140.0 | 19.0 | 135.0 | 18.0 |
| Maximum | 164 | 43 | 176 | 50 | 193 | 55 | 178 | 60 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 114.6 | 1.9 | 120.2 | 3.4 | 120.7 | 8.8 | 115.4 | 6.9 |
| SD | 17.90 | 18.57 | 28.52 | 17.29 | 30.71 | 22.33 | 30.69 | 18.68 |
| Minimum | 75 | -62 | 40 | -35 | 66 | -48 | 61 | -38 |
| Q1 | 102.0 | -11.0 | 102.0 | -10.0 | 95.0 | -5.0 | 93.0 | -3.0 |
| Median | 112.0 | 3.0 | 122.0 | 0.0 | 119.0 | 6.0 | 117.0 | 5.5 |
| Q3 | 128.0 | 12.0 | 140.0 | 13.0 | 137.0 | 24.0 | 136.0 | 19.0 |
| Maximum | 163 | 53 | 177 | 46 | 213 | 64 | 190 | 46 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDL Cholesterol (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 112.2 | 0.8 | 109.3 | -6.3 | 110.1 | -1.4 | 108.7 | 0.3 |
| SD | 20.07 | 17.37 | 27.35 | 17.19 | 26.21 | 16.43 | 24.66 | 17.84 |
| Minimum | 72 | -61 | 34 | -51 | 58 | -45 | 61 | -60 |
| Q1 | 100.0 | -10.0 | 89.5 | -16.5 | 89.0 | -14.0 | 92.0 | -9.0 |
| Median | 108.0 | 0.0 | 115.0 | -5.5 | 107.0 | -2.0 | 105.5 | -1.0 |
| Q3 | 125.0 | 14.0 | 125.0 | 2.0 | 128.0 | 10.0 | 126.0 | 12.0 |
| Maximum | 171 | 32 | 171 | 45 | 172 | 36 | 163 | 39 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 95.1 | | 99.8 | | 79.0 | | 93.1 | |
| SD | 56.56 | | 62.50 | | 33.97 | | 57.08 | |
| Minimum | 27 | | 35 | | 32 | | 34 | |
| Q1 | 59.0 | | 63.0 | | 60.0 | | 54.0 | |
| Median | 79.0 | | 86.5 | | 70.0 | | 75.0 | |
| Q3 | 106.0 | | 115.0 | | 89.0 | | 112.0 | |
| Maximum | 279 | | 418 | | 201 | | 276 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 89.7 | -5.3 | 104.3 | 4.4 | 93.1 | 14.1 | 95.0 | 1.9 |
| SD | 43.87 | 42.33 | 69.94 | 61.44 | 42.11 | 39.98 | 49.58 | 43.49 |
| Minimum | 31 | -174 | 31 | -189 | 34 | -86 | 28 | -134 |
| Q1 | 61.0 | -19.0 | 56.0 | -20.5 | 64.0 | -10.0 | 57.0 | -14.0 |
| Median | 78.0 | -2.0 | 84.0 | 1.5 | 84.0 | 11.0 | 86.5 | 4.5 |
| Q3 | 107.0 | 16.0 | 118.5 | 23.5 | 113.0 | 38.0 | 110.0 | 27.0 |
| Maximum | 251 | 77 | 311 | 207 | 213 | 127 | 235 | 92 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 98.4 | 3.4 | 108.4 | 8.5 | 96.0 | 16.7 | 106.8 | 13.7 |
| SD | 66.17 | 51.75 | 65.00 | 58.06 | 49.88 | 39.26 | 81.93 | 55.39 |
| Minimum | 34 | -135 | 30 | -229 | 34 | -85 | 36 | -135 |
| Q1 | 60.5 | -17.5 | 56.0 | -7.0 | 58.0 | -7.0 | 61.0 | -9.0 |
| Median | 75.0 | 0.0 | 87.0 | 4.5 | 84.0 | 10.5 | 81.5 | 12.5 |
| Q3 | 116.5 | 23.5 | 144.0 | 21.0 | 127.0 | 40.0 | 125.0 | 29.0 |
| Maximum | 447 | 233 | 292 | 194 | 238 | 113 | 570 | 294 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 94.8 | -0.3 | 115.2 | 14.0 | 103.3 | 23.7 | 104.5 | 11.4 |
| SD | 51.19 | 37.16 | 93.60 | 95.13 | 55.32 | 43.57 | 59.82 | 41.31 |
| Minimum | 39 | -107 | 40 | -219 | 32 | -104 | 28 | -61 |
| Q1 | 62.0 | -21.0 | 68.0 | -20.0 | 71.0 | 0.0 | 56.0 | -12.0 |
| Median | 83.0 | 4.0 | 90.0 | 10.0 | 94.0 | 19.0 | 95.0 | 1.5 |
| Q3 | 119.0 | 20.0 | 144.0 | 31.0 | 125.0 | 38.0 | 131.0 | 29.0 |
| Maximum | 259 | 61 | 648 | 543 | 358 | 157 | 285 | 163 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 97.3 | 2.2 | 106.6 | 6.8 | 93.7 | 14.7 | 96.6 | 3.5 |
| SD | 56.34 | 42.30 | 60.41 | 55.00 | 42.22 | 41.61 | 59.65 | 42.07 |
| Minimum | 30 | -97 | 35 | -149 | 41 | -96 | 28 | -129 |
| Q1 | 57.0 | -17.0 | 63.5 | -19.5 | 62.0 | -8.0 | 51.0 | -20.0 |
| Median | 82.0 | 2.0 | 92.5 | 4.5 | 82.0 | 12.0 | 77.5 | 2.5 |
| Q3 | 115.0 | 20.0 | 127.5 | 35.0 | 119.0 | 31.0 | 127.0 | 25.0 |
| Maximum | 257 | 132 | 301 | 151 | 242 | 115 | 310 | 108 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 94.5 | | 95.6 | | 101.4 | | 93.3 | |
| SD | 8.89 | | 9.15 | | 33.44 | | 11.62 | |
| Minimum | 63 | | 83 | | 81 | | 60 | |
| Q1 | 89.0 | | 90.0 | | 90.0 | | 88.0 | |
| Median | 94.0 | | 93.0 | | 94.0 | | 92.0 | |
| Q3 | 100.0 | | 98.5 | | 102.0 | | 96.0 | |
| Maximum | 115 | | 128 | | 328 | | 133 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 94.0 | -0.5 | 95.5 | -0.1 | 98.7 | -2.7 | 97.3 | 4.1 |
| SD | 9.85 | 10.02 | 10.15 | 11.03 | 18.84 | 19.01 | 19.66 | 15.43 |
| Minimum | 72 | -19 | 77 | -28 | 72 | -123 | 68 | -25 |
| Q1 | 88.0 | -6.0 | 89.0 | -4.5 | 90.0 | -5.0 | 89.0 | -3.0 |
| Median | 92.0 | 0.0 | 93.5 | -1.0 | 96.0 | -1.0 | 93.5 | 2.0 |
| Q3 | 99.0 | 3.0 | 101.5 | 6.0 | 102.0 | 6.0 | 102.0 | 9.0 |
| Maximum | 127 | 33 | 122 | 25 | 205 | 16 | 215 | 82 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 94.2 | -0.4 | 97.2 | 1.7 | 98.6 | -3.1 | 98.7 | 5.4 |
| SD | 11.24 | 9.98 | 9.27 | 11.02 | 25.47 | 13.43 | 27.17 | 22.55 |
| Minimum | 71 | -27 | 85 | -26 | 76 | -73 | 80 | -37 |
| Q1 | 88.0 | -5.0 | 91.0 | -4.0 | 89.0 | -6.0 | 88.0 | -1.0 |
| Median | 92.0 | -0.5 | 95.0 | 1.0 | 92.5 | -2.0 | 95.0 | 4.0 |
| Q3 | 97.0 | 3.0 | 101.0 | 6.5 | 101.0 | 2.0 | 100.0 | 7.0 |
| Maximum | 131 | 25 | 129 | 36 | 255 | 25 | 286 | 153 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 95.5 | 1.0 | 96.6 | 0.9 | 98.1 | -3.8 | 96.4 | 3.1 |
| SD | 11.48 | 11.76 | 11.10 | 11.21 | 16.25 | 28.61 | 15.78 | 12.45 |
| Minimum | 69 | -23 | 79 | -28 | 79 | -193 | 83 | -22 |
| Q1 | 90.0 | -4.0 | 89.0 | -4.0 | 88.0 | -7.0 | 88.0 | -2.0 |
| Median | 94.0 | 0.0 | 95.0 | 0.0 | 94.0 | -1.0 | 93.0 | 2.0 |
| Q3 | 100.0 | 5.0 | 101.0 | 4.0 | 102.0 | 5.0 | 99.0 | 7.0 |
| Maximum | 140 | 44 | 146 | 49 | 172 | 30 | 190 | 57 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 98.2 | 3.8 | 96.9 | 1.3 | 101.6 | 0.2 | 94.1 | 0.8 |
| SD | 14.96 | 15.41 | 15.41 | 14.01 | 26.97 | 36.11 | 14.79 | 13.21 |
| Minimum | 81 | -20 | 76 | -23 | 74 | -219 | 76 | -45 |
| Q1 | 90.0 | -6.0 | 89.0 | -4.5 | 89.0 | -6.0 | 84.0 | -5.0 |
| Median | 95.0 | 1.0 | 93.5 | 0.0 | 96.0 | 1.0 | 91.0 | -0.5 |
| Q3 | 100.0 | 8.0 | 98.5 | 4.0 | 108.0 | 9.0 | 99.0 | 6.0 |
| Maximum | 170 | 72 | 167 | 58 | 258 | 116 | 168 | 35 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 0.601 | | 0.598 | | 0.593 | | 0.591 | |
| SD | 0.0902 | | 0.0765 | | 0.0785 | | 0.0748 | |
| Minimum | 0.44 | | 0.44 | | 0.46 | | 0.42 | |
| Q1 | 0.540 | | 0.550 | | 0.530 | | 0.550 | |
| Median | 0.590 | | 0.595 | | 0.590 | | 0.590 | |
| Q3 | 0.670 | | 0.645 | | 0.650 | | 0.630 | |
| Maximum | 0.82 | | 0.86 | | 0.78 | | 0.79 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 0.585 | -0.016 | 0.599 | 0.001 | 0.597 | 0.003 | 0.609 | 0.018 |
| SD | 0.0930 | 0.0469 | 0.0654 | 0.0491 | 0.0841 | 0.0501 | 0.0782 | 0.0452 |
| Minimum | 0.40 | -0.18 | 0.47 | -0.10 | 0.44 | -0.12 | 0.45 | -0.12 |
| Q1 | 0.510 | -0.040 | 0.565 | -0.025 | 0.530 | -0.020 | 0.560 | -0.010 |
| Median | 0.570 | -0.010 | 0.590 | 0.000 | 0.590 | 0.010 | 0.600 | 0.020 |
| Q3 | 0.640 | 0.010 | 0.640 | 0.025 | 0.660 | 0.040 | 0.660 | 0.050 |
| Maximum | 0.79 | 0.07 | 0.76 | 0.13 | 0.79 | 0.09 | 0.83 | 0.11 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 0.593 | -0.011 | 0.598 | 0.000 | 0.610 | 0.016 | 0.607 | 0.016 |
| SD | 0.0743 | 0.0454 | 0.0656 | 0.0659 | 0.0853 | 0.0407 | 0.0766 | 0.0503 |
| Minimum | 0.43 | -0.13 | 0.46 | -0.19 | 0.47 | -0.07 | 0.46 | -0.13 |
| Q1 | 0.545 | -0.040 | 0.560 | -0.040 | 0.550 | -0.010 | 0.550 | -0.010 |
| Median | 0.580 | -0.010 | 0.590 | 0.000 | 0.595 | 0.020 | 0.605 | 0.020 |
| Q3 | 0.650 | 0.020 | 0.670 | 0.045 | 0.680 | 0.040 | 0.660 | 0.050 |
| Maximum | 0.78 | 0.07 | 0.72 | 0.17 | 0.80 | 0.12 | 0.79 | 0.11 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 0.592 | -0.013 | 0.602 | 0.003 | 0.610 | 0.018 | 0.603 | 0.012 |
| SD | 0.0867 | 0.0535 | 0.0662 | 0.0471 | 0.0779 | 0.0421 | 0.0831 | 0.0397 |
| Minimum | 0.44 | -0.20 | 0.49 | -0.10 | 0.47 | -0.08 | 0.41 | -0.06 |
| Q1 | 0.530 | -0.030 | 0.560 | -0.040 | 0.560 | 0.000 | 0.550 | -0.020 |
| Median | 0.570 | -0.010 | 0.590 | 0.000 | 0.600 | 0.010 | 0.600 | 0.010 |
| Q3 | 0.640 | 0.020 | 0.650 | 0.030 | 0.650 | 0.040 | 0.660 | 0.030 |
| Maximum | 0.81 | 0.10 | 0.76 | 0.11 | 0.84 | 0.13 | 0.81 | 0.13 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 0.606 | 0.005 | 0.600 | 0.002 | 0.611 | 0.018 | 0.603 | 0.012 |
| SD | 0.0867 | 0.0614 | 0.0769 | 0.0609 | 0.0854 | 0.0540 | 0.0747 | 0.0480 |
| Minimum | 0.47 | -0.24 | 0.44 | -0.14 | 0.47 | -0.08 | 0.46 | -0.08 |
| Q1 | 0.540 | -0.020 | 0.550 | -0.035 | 0.550 | -0.020 | 0.560 | -0.020 |
| Median | 0.600 | 0.010 | 0.600 | -0.010 | 0.610 | 0.010 | 0.600 | 0.005 |
| Q3 | 0.660 | 0.030 | 0.640 | 0.040 | 0.670 | 0.060 | 0.650 | 0.040 |
| Maximum | 0.81 | 0.13 | 0.81 | 0.17 | 0.84 | 0.17 | 0.78 | 0.13 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood Urea Nitrogen (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 11.41 | | 11.45 | | 11.67 | | 11.45 | |
| SD | 2.982 | | 2.613 | | 3.044 | | 2.464 | |
| Minimum | 7.2 | | 6.7 | | 6.9 | | 7.6 | |
| Q1 | 9.20 | | 9.60 | | 9.50 | | 9.50 | |
| Median | 11.20 | | 11.85 | | 11.10 | | 11.15 | |
| Q3 | 13.00 | | 12.65 | | 13.40 | | 13.10 | |
| Maximum | 17.7 | | 20.1 | | 23.3 | | 18.0 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 11.16 | -0.25 | 12.42 | 0.97 | 12.28 | 0.60 | 12.70 | 1.25 |
| SD | 2.717 | 2.317 | 2.927 | 2.841 | 2.493 | 3.067 | 2.865 | 2.404 |
| Minimum | 6.4 | -5.4 | 7.6 | -5.1 | 7.5 | -8.4 | 4.8 | -4.2 |
| Q1 | 9.10 | -1.80 | 10.25 | -1.25 | 10.70 | -1.10 | 10.60 | -0.50 |
| Median | 11.10 | 0.00 | 11.60 | 1.20 | 12.20 | 0.50 | 12.85 | 1.00 |
| Q3 | 12.80 | 0.90 | 14.80 | 2.55 | 13.80 | 2.70 | 14.80 | 2.70 |
| Maximum | 17.7 | 5.0 | 20.4 | 8.3 | 18.6 | 7.2 | 19.8 | 7.2 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 10.82 | -0.59 | 11.76 | 0.31 | 12.17 | 0.53 | 12.56 | 1.11 |
| SD | 2.763 | 2.262 | 3.154 | 2.476 | 2.469 | 2.630 | 2.517 | 2.263 |
| Minimum | 6.5 | -6.2 | 6.4 | -5.3 | 8.2 | -8.5 | 7.2 | -4.5 |
| Q1 | 8.80 | -1.75 | 9.55 | -1.60 | 10.30 | -1.30 | 10.60 | -0.40 |
| Median | 10.55 | -0.40 | 11.45 | 0.55 | 11.95 | 0.80 | 12.70 | 1.20 |
| Q3 | 12.40 | 0.90 | 13.75 | 1.55 | 13.70 | 2.20 | 14.00 | 2.30 |
| Maximum | 21.7 | 4.3 | 19.3 | 7.1 | 17.3 | 5.5 | 20.3 | 6.3 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 11.48 | -0.01 | 11.72 | 0.17 | 12.61 | 0.89 | 12.01 | 0.57 |
| SD | 2.671 | 2.536 | 2.251 | 2.249 | 3.064 | 3.339 | 2.282 | 2.618 |
| Minimum | 7.3 | -6.0 | 7.6 | -4.3 | 7.8 | -9.9 | 7.3 | -4.8 |
| Q1 | 9.90 | -1.70 | 10.40 | -1.70 | 10.20 | -0.80 | 10.30 | -1.40 |
| Median | 10.90 | -0.10 | 11.50 | 0.30 | 12.20 | 0.70 | 11.90 | 0.50 |
| Q3 | 12.50 | 1.00 | 13.10 | 1.80 | 14.90 | 2.90 | 13.50 | 3.00 |
| Maximum | 18.5 | 8.2 | 17.0 | 4.5 | 19.2 | 8.2 | 16.7 | 6.9 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood Urea Nitrogen (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 10.78 | -0.64 | 11.78 | 0.33 | 12.00 | 0.33 | 11.16 | -0.29 |
| SD | 2.665 | 2.276 | 2.600 | 2.613 | 3.006 | 3.293 | 3.050 | 2.632 |
| Minimum | 4.5 | -7.5 | 7.3 | -5.8 | 7.2 | -9.0 | 5.2 | -5.4 |
| Q1 | 9.00 | -1.90 | 9.95 | -1.70 | 9.60 | -1.80 | 9.10 | -2.20 |
| Median | 10.60 | -0.60 | 11.35 | 0.35 | 11.70 | 0.30 | 11.15 | -0.65 |
| Q3 | 11.90 | 0.80 | 13.80 | 2.00 | 14.60 | 3.00 | 12.80 | 1.20 |
| Maximum | 18.4 | 4.9 | 17.7 | 5.7 | 20.1 | 6.4 | 21.9 | 6.2 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: CK(CPK) (U/L)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 74.7 | | 83.1 | | 75.5 | | 84.1 | |
| SD | 26.20 | | 27.89 | | 28.73 | | 32.13 | |
| Minimum | 34 | | 32 | | 40 | | 31 | |
| Q1 | 56.0 | | 65.0 | | 59.0 | | 63.0 | |
| Median | 69.0 | | 77.5 | | 68.0 | | 77.5 | |
| Q3 | 88.0 | | 90.5 | | 83.0 | | 100.0 | |
| Maximum | 150 | | 174 | | 216 | | 165 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 75.7 | 1.0 | 82.2 | -0.9 | 77.0 | 1.5 | 85.9 | 1.7 |
| SD | 27.34 | 20.93 | 28.64 | 25.94 | 25.63 | 22.76 | 27.24 | 21.54 |
| Minimum | 38 | -71 | 35 | -85 | 34 | -118 | 40 | -72 |
| Q1 | 57.0 | -9.0 | 61.0 | -10.5 | 60.0 | -6.0 | 64.0 | -7.0 |
| Median | 69.0 | 1.0 | 79.0 | 1.5 | 71.0 | 3.0 | 82.5 | 2.5 |
| Q3 | 86.0 | 8.0 | 93.5 | 11.0 | 93.0 | 11.0 | 102.0 | 12.0 |
| Maximum | 162 | 84 | 172 | 106 | 179 | 42 | 167 | 57 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 72.7 | -2.2 | 82.5 | -0.6 | 93.1 | 20.3 | 83.7 | -0.4 |
| SD | 23.32 | 17.78 | 29.93 | 26.19 | 113.90 | 111.15 | 27.41 | 24.91 |
| Minimum | 32 | -66 | 38 | -90 | 32 | -43 | 44 | -80 |
| Q1 | 55.5 | -8.0 | 59.5 | -12.0 | 60.0 | -6.0 | 68.0 | -15.0 |
| Median | 68.5 | -1.5 | 76.0 | -1.5 | 73.0 | 3.0 | 77.5 | 2.0 |
| Q3 | 86.0 | 8.5 | 104.0 | 8.5 | 89.0 | 11.0 | 92.0 | 12.0 |
| Maximum | 146 | 38 | 153 | 85 | 885 | 801 | 204 | 67 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 75.3 | 0.4 | 95.9 | 13.0 | 77.2 | 4.2 | 86.3 | 2.2 |
| SD | 38.22 | 30.75 | 72.23 | 72.02 | 26.07 | 21.34 | 29.68 | 21.65 |
| Minimum | 25 | -62 | 36 | -85 | 33 | -60 | 36 | -72 |
| Q1 | 53.0 | -12.0 | 66.0 | -10.0 | 63.0 | -6.0 | 66.0 | -8.0 |
| Median | 67.0 | -2.0 | 86.0 | 4.0 | 74.0 | 5.0 | 80.5 | 3.0 |
| Q3 | 81.0 | 11.0 | 102.0 | 18.0 | 88.0 | 12.0 | 102.0 | 14.0 |
| Maximum | 281 | 144 | 535 | 469 | 181 | 85 | 187 | 53 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: CK(CPK) (U/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 73.8 | -0.9 | 81.9 | -1.1 | 71.4 | -4.0 | 85.2 | 1.1 |
| SD | 30.43 | 27.53 | 37.40 | 33.75 | 26.18 | 30.28 | 68.97 | 64.94 |
| Minimum | 34 | -69 | 28 | -77 | 30 | -130 | 29 | -82 |
| Q1 | 50.0 | -14.0 | 57.5 | -15.5 | 54.0 | -13.0 | 57.0 | -19.0 |
| Median | 70.0 | -3.0 | 79.5 | -5.0 | 68.0 | -3.0 | 74.0 | -8.0 |
| Q3 | 84.0 | 8.0 | 97.5 | 7.5 | 83.0 | 9.0 | 86.0 | 2.0 |
| Maximum | 183 | 127 | 216 | 143 | 162 | 94 | 502 | 402 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Uric Acid (mg/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 4.24 | | 4.18 | | 4.20 | | 4.18 | |
| SD | 0.810 | | 1.029 | | 1.072 | | 0.759 | |
| Minimum | 2.3 | | 1.9 | | 0.7 | | 2.4 | |
| Q1 | 3.60 | | 3.50 | | 3.60 | | 3.70 | |
| Median | 4.10 | | 4.00 | | 4.10 | | 4.10 | |
| Q3 | 4.80 | | 4.90 | | 4.70 | | 4.80 | |
| Maximum | 5.9 | | 7.3 | | 7.3 | | 5.6 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 4.17 | -0.06 | 4.54 | 0.35 | 4.23 | 0.03 | 4.44 | 0.26 |
| SD | 0.808 | 0.585 | 1.060 | 0.578 | 0.986 | 0.660 | 0.810 | 0.573 |
| Minimum | 2.6 | -1.1 | 2.2 | -0.6 | 0.6 | -1.6 | 2.4 | -0.6 |
| Q1 | 3.50 | -0.50 | 4.00 | -0.10 | 3.60 | -0.40 | 4.00 | -0.20 |
| Median | 4.10 | 0.00 | 4.50 | 0.25 | 4.30 | 0.00 | 4.60 | 0.10 |
| Q3 | 4.70 | 0.40 | 5.25 | 0.70 | 4.90 | 0.40 | 5.00 | 0.60 |
| Maximum | 5.9 | 1.2 | 7.2 | 2.0 | 5.8 | 1.5 | 5.8 | 1.6 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 4.19 | -0.06 | 4.40 | 0.22 | 4.43 | 0.22 | 4.48 | 0.30 |
| SD | 0.862 | 0.591 | 1.169 | 0.661 | 1.044 | 0.641 | 0.788 | 0.541 |
| Minimum | 2.6 | -1.3 | 2.1 | -1.0 | 0.6 | -1.6 | 2.3 | -0.8 |
| Q1 | 3.50 | -0.45 | 3.65 | -0.15 | 4.00 | -0.20 | 4.10 | -0.10 |
| Median | 4.00 | 0.00 | 4.25 | 0.10 | 4.35 | 0.20 | 4.60 | 0.25 |
| Q3 | 4.90 | 0.30 | 5.15 | 0.60 | 5.20 | 0.70 | 4.90 | 0.70 |
| Maximum | 6.2 | 1.8 | 8.4 | 1.8 | 6.4 | 1.6 | 5.9 | 1.3 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 4.29 | 0.03 | 4.41 | 0.23 | 4.44 | 0.25 | 4.59 | 0.41 |
| SD | 0.886 | 0.582 | 1.067 | 0.589 | 0.998 | 0.643 | 0.865 | 0.580 |
| Minimum | 2.7 | -1.3 | 2.7 | -1.3 | 0.7 | -1.3 | 2.5 | -0.5 |
| Q1 | 3.60 | -0.30 | 3.70 | -0.30 | 3.80 | 0.00 | 4.10 | -0.10 |
| Median | 4.20 | 0.00 | 4.30 | 0.20 | 4.40 | 0.20 | 4.65 | 0.40 |
| Q3 | 4.90 | 0.40 | 5.10 | 0.60 | 5.00 | 0.50 | 5.30 | 0.70 |
| Maximum | 6.3 | 1.5 | 8.4 | 1.8 | 6.5 | 2.3 | 6.7 | 1.9 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Uric Acid (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 4.29 | 0.06 | 4.34 | 0.16 | 4.29 | 0.09 | 4.40 | 0.22 |
| SD | 0.753 | 0.629 | 1.018 | 0.532 | 1.001 | 0.669 | 0.758 | 0.552 |
| Minimum | 2.7 | -1.7 | 2.3 | -1.1 | 0.8 | -1.6 | 2.6 | -1.0 |
| Q1 | 3.80 | -0.30 | 3.70 | -0.20 | 3.70 | -0.30 | 4.00 | -0.10 |
| Median | 4.30 | 0.10 | 4.15 | 0.10 | 4.20 | 0.20 | 4.30 | 0.00 |
| Q3 | 4.90 | 0.50 | 4.80 | 0.50 | 4.80 | 0.40 | 4.80 | 0.60 |
| Maximum | 5.9 | 1.7 | 7.9 | 1.7 | 7.0 | 2.8 | 6.0 | 1.8 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 141.3 | | 141.1 | | 141.1 | | 141.2 | |
| SD | 1.58 | | 1.55 | | 1.44 | | 1.55 | |
| Minimum | 137 | | 138 | | 138 | | 137 | |
| Q1 | 140.0 | | 140.0 | | 140.0 | | 140.0 | |
| Median | 141.0 | | 141.0 | | 141.0 | | 141.0 | |
| Q3 | 142.0 | | 142.0 | | 142.0 | | 142.0 | |
| Maximum | 146 | | 145 | | 145 | | 145 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 141.1 | -0.2 | 141.0 | -0.1 | 141.7 | 0.7 | 142.0 | 0.8 |
| SD | 1.39 | 1.72 | 1.74 | 1.40 | 1.67 | 1.87 | 1.40 | 1.73 |
| Minimum | 138 | -4 | 136 | -4 | 138 | -3 | 138 | -5 |
| Q1 | 140.0 | -2.0 | 140.0 | -1.0 | 141.0 | 0.0 | 141.0 | 0.0 |
| Median | 141.0 | 0.0 | 141.0 | 0.0 | 142.0 | 0.0 | 142.0 | 1.0 |
| Q3 | 142.0 | 1.0 | 142.0 | 1.0 | 143.0 | 2.0 | 143.0 | 2.0 |
| Maximum | 144 | 3 | 146 | 4 | 147 | 6 | 145 | 4 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 140.8 | -0.4 | 141.2 | 0.1 | 141.4 | 0.4 | 141.9 | 0.7 |
| SD | 1.58 | 1.90 | 1.84 | 1.75 | 1.41 | 1.52 | 1.57 | 1.70 |
| Minimum | 135 | -4 | 137 | -4 | 138 | -3 | 137 | -6 |
| Q1 | 140.0 | -1.5 | 140.0 | -1.0 | 141.0 | -1.0 | 141.0 | 0.0 |
| Median | 141.0 | -0.5 | 141.0 | 0.0 | 141.0 | 1.0 | 142.0 | 1.0 |
| Q3 | 142.0 | 1.0 | 142.5 | 1.0 | 142.0 | 1.0 | 143.0 | 2.0 |
| Maximum | 144 | 4 | 147 | 3 | 145 | 4 | 145 | 5 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 141.0 | -0.2 | 141.3 | 0.2 | 142.0 | 0.9 | 142.0 | 0.9 |
| SD | 1.44 | 1.77 | 1.89 | 2.06 | 1.64 | 1.66 | 1.36 | 1.68 |
| Minimum | 137 | -4 | 136 | -4 | 138 | -3 | 139 | -3 |
| Q1 | 140.0 | -1.0 | 140.0 | -1.0 | 141.0 | 0.0 | 141.0 | 0.0 |
| Median | 141.0 | 0.0 | 141.0 | 0.0 | 142.0 | 1.0 | 142.0 | 1.0 |
| Q3 | 142.0 | 1.0 | 142.0 | 2.0 | 143.0 | 2.0 | 143.0 | 2.0 |
| Maximum | 144 | 4 | 147 | 6 | 147 | 5 | 145 | 4 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 140.8 | -0.5 | 140.7 | -0.4 | 141.1 | 0.0 | 141.0 | -0.2 |
| SD | 1.79 | 2.00 | 1.51 | 1.44 | 1.48 | 1.61 | 1.76 | 2.01 |
| Minimum | 136 | -5 | 137 | -5 | 138 | -3 | 137 | -4 |
| Q1 | 139.0 | -2.0 | 140.0 | -1.0 | 140.0 | -1.0 | 140.0 | -2.0 |
| Median | 141.0 | -1.0 | 141.0 | -0.5 | 141.0 | 0.0 | 141.0 | 0.0 |
| Q3 | 142.0 | 1.0 | 142.0 | 0.0 | 142.0 | 1.0 | 142.0 | 1.0 |
| Maximum | 145 | 4 | 144 | 3 | 144 | 3 | 145 | 4 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 4.11 | | 4.09 | | 4.12 | | 4.16 | |
| SD | 0.247 | | 0.296 | | 0.352 | | 0.227 | |
| Minimum | 3.5 | | 3.1 | | 3.3 | | 3.6 | |
| Q1 | 3.90 | | 3.90 | | 3.90 | | 4.00 | |
| Median | 4.10 | | 4.15 | | 4.10 | | 4.20 | |
| Q3 | 4.30 | | 4.20 | | 4.30 | | 4.30 | |
| Maximum | 4.7 | | 4.8 | | 5.1 | | 4.9 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 4.16 | 0.05 | 4.18 | 0.08 | 4.20 | 0.08 | 4.21 | 0.05 |
| SD | 0.236 | 0.285 | 0.306 | 0.294 | 0.277 | 0.303 | 0.259 | 0.265 |
| Minimum | 3.5 | -0.9 | 3.4 | -0.5 | 3.4 | -0.6 | 3.7 | -0.5 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.10 | 4.00 | -0.10 | 4.10 | -0.10 |
| Median | 4.10 | 0.10 | 4.20 | 0.10 | 4.20 | 0.10 | 4.20 | 0.05 |
| Q3 | 4.30 | 0.20 | 4.40 | 0.25 | 4.40 | 0.30 | 4.40 | 0.20 |
| Maximum | 4.7 | 0.6 | 4.8 | 0.7 | 4.9 | 0.7 | 4.9 | 0.5 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 4.15 | 0.05 | 4.21 | 0.11 | 4.21 | 0.08 | 4.24 | 0.07 |
| SD | 0.290 | 0.324 | 0.319 | 0.359 | 0.309 | 0.294 | 0.246 | 0.239 |
| Minimum | 3.5 | -0.8 | 3.7 | -0.5 | 3.3 | -0.7 | 3.7 | -0.3 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.10 | 4.10 | -0.10 | 4.10 | -0.10 |
| Median | 4.10 | 0.00 | 4.15 | 0.05 | 4.20 | 0.10 | 4.20 | 0.10 |
| Q3 | 4.30 | 0.20 | 4.30 | 0.30 | 4.40 | 0.30 | 4.40 | 0.20 |
| Maximum | 4.9 | 0.8 | 5.1 | 1.3 | 5.0 | 1.0 | 4.8 | 0.7 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 4.15 | 0.04 | 4.22 | 0.13 | 4.18 | 0.05 | 4.15 | -0.01 |
| SD | 0.276 | 0.310 | 0.283 | 0.287 | 0.299 | 0.278 | 0.266 | 0.268 |
| Minimum | 3.2 | -0.6 | 3.7 | -0.4 | 3.5 | -0.8 | 3.5 | -0.6 |
| Q1 | 4.00 | -0.20 | 4.00 | -0.10 | 4.00 | -0.10 | 4.00 | -0.20 |
| Median | 4.10 | 0.10 | 4.20 | 0.10 | 4.20 | 0.10 | 4.20 | 0.00 |
| Q3 | 4.30 | 0.30 | 4.40 | 0.30 | 4.30 | 0.20 | 4.30 | 0.20 |
| Maximum | 4.7 | 1.0 | 4.9 | 1.0 | 5.0 | 0.6 | 4.7 | 0.6 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 4.14 | 0.04 | 4.21 | 0.12 | 4.19 | 0.07 | 4.18 | 0.01 |
| SD | 0.285 | 0.334 | 0.281 | 0.295 | 0.353 | 0.323 | 0.282 | 0.293 |
| Minimum | 3.5 | -0.8 | 3.6 | -0.5 | 3.4 | -0.9 | 3.5 | -0.7 |
| Q1 | 3.90 | -0.10 | 4.10 | -0.10 | 4.00 | -0.10 | 4.00 | -0.20 |
| Median | 4.10 | 0.00 | 4.20 | 0.10 | 4.20 | 0.00 | 4.20 | 0.00 |
| Q3 | 4.40 | 0.20 | 4.45 | 0.40 | 4.40 | 0.20 | 4.40 | 0.20 |
| Maximum | 4.7 | 0.9 | 5.0 | 0.7 | 5.1 | 0.8 | 5.0 | 0.6 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 104.0 | | 103.6 | | 103.7 | | 103.9 | |
| SD | 1.94 | | 2.60 | | 1.85 | | 2.05 | |
| Minimum | 99 | | 97 | | 99 | | 99 | |
| Q1 | 103.0 | | 102.5 | | 102.0 | | 102.0 | |
| Median | 104.0 | | 104.0 | | 104.0 | | 104.0 | |
| Q3 | 105.0 | | 105.0 | | 105.0 | | 105.0 | |
| Maximum | 109 | | 110 | | 107 | | 109 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 103.6 | -0.4 | 103.5 | -0.2 | 103.6 | -0.2 | 103.6 | -0.3 |
| SD | 2.14 | 2.25 | 2.47 | 2.17 | 1.85 | 1.82 | 2.22 | 2.29 |
| Minimum | 98 | -5 | 97 | -4 | 100 | -4 | 99 | -6 |
| Q1 | 102.0 | -2.0 | 101.5 | -1.0 | 102.0 | -1.0 | 102.0 | -2.0 |
| Median | 104.0 | 0.0 | 104.0 | 0.0 | 103.0 | 0.0 | 104.0 | 0.0 |
| Q3 | 105.0 | 1.0 | 105.0 | 1.0 | 105.0 | 1.0 | 105.0 | 1.0 |
| Maximum | 108 | 5 | 109 | 6 | 107 | 4 | 109 | 5 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 103.9 | 0.0 | 103.7 | 0.0 | 103.5 | -0.2 | 103.6 | -0.4 |
| SD | 2.03 | 2.37 | 1.91 | 2.51 | 1.80 | 2.10 | 2.10 | 2.20 |
| Minimum | 98 | -6 | 100 | -8 | 99 | -4 | 98 | -6 |
| Q1 | 103.0 | -2.0 | 102.0 | -1.0 | 103.0 | -2.0 | 102.0 | -2.0 |
| Median | 104.0 | 0.0 | 103.5 | 0.0 | 104.0 | 0.0 | 104.0 | 0.0 |
| Q3 | 105.0 | 1.5 | 105.0 | 1.5 | 104.0 | 1.0 | 105.0 | 1.0 |
| Maximum | 108 | 5 | 107 | 6 | 107 | 5 | 108 | 6 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 103.6 | -0.3 | 104.0 | 0.4 | 103.6 | -0.1 | 103.4 | -0.5 |
| SD | 2.08 | 2.23 | 1.85 | 2.30 | 2.00 | 1.96 | 2.04 | 1.88 |
| Minimum | 98 | -6 | 98 | -6 | 100 | -4 | 97 | -5 |
| Q1 | 103.0 | -2.0 | 103.0 | -1.0 | 102.0 | -1.0 | 102.0 | -2.0 |
| Median | 104.0 | 0.0 | 104.0 | 0.0 | 104.0 | -1.0 | 104.0 | 0.0 |
| Q3 | 105.0 | 1.0 | 105.0 | 2.0 | 105.0 | 1.0 | 105.0 | 1.0 |
| Maximum | 107 | 5 | 108 | 6 | 108 | 4 | 108 | 3 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 104.1 | 0.1 | 104.3 | 0.6 | 104.1 | 0.4 | 104.6 | 0.7 |
| SD | 2.05 | 2.28 | 1.92 | 2.22 | 1.89 | 2.14 | 2.14 | 2.23 |
| Minimum | 99 | -5 | 99 | -7 | 101 | -4 | 98 | -6 |
| Q1 | 103.0 | -1.0 | 103.0 | 0.0 | 103.0 | -1.0 | 104.0 | -1.0 |
| Median | 104.0 | 0.0 | 105.0 | 1.0 | 104.0 | 1.0 | 104.0 | 1.0 |
| Q3 | 106.0 | 2.0 | 105.0 | 2.0 | 106.0 | 2.0 | 106.0 | 2.0 |
| Maximum | 108 | 6 | 108 | 6 | 109 | 5 | 110 | 6 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

# 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 8.98 | | 9.03 | | 8.99 | | 8.99 | |
| SD | 0.385 | | 0.372 | | 0.292 | | 0.342 | |
| Minimum | 8.2 | | 8.2 | | 8.2 | | 7.9 | |
| Q1 | 8.70 | | 8.80 | | 8.80 | | 8.80 | |
| Median | 8.90 | | 9.00 | | 9.00 | | 9.00 | |
| Q3 | 9.10 | | 9.25 | | 9.20 | | 9.20 | |
| Maximum | 10.1 | | 9.9 | | 9.7 | | 9.9 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 8.93 | -0.04 | 9.05 | 0.02 | 9.24 | 0.24 | 9.27 | 0.28 |
| SD | 0.330 | 0.332 | 0.309 | 0.333 | 0.266 | 0.275 | 0.296 | 0.357 |
| Minimum | 8.2 | -1.2 | 8.2 | -0.8 | 8.7 | -0.4 | 8.5 | -0.6 |
| Q1 | 8.70 | -0.20 | 8.90 | -0.20 | 9.00 | 0.10 | 9.10 | 0.00 |
| Median | 8.90 | 0.00 | 9.05 | 0.00 | 9.20 | 0.20 | 9.20 | 0.30 |
| Q3 | 9.10 | 0.10 | 9.20 | 0.30 | 9.40 | 0.40 | 9.50 | 0.50 |
| Maximum | 9.7 | 0.7 | 9.9 | 0.7 | 9.9 | 0.9 | 9.9 | 1.0 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 8.97 | -0.02 | 9.12 | 0.09 | 9.30 | 0.31 | 9.42 | 0.43 |
| SD | 0.327 | 0.300 | 0.344 | 0.355 | 0.318 | 0.315 | 0.310 | 0.383 |
| Minimum | 8.1 | -0.9 | 8.4 | -0.8 | 8.6 | -0.5 | 8.7 | -0.5 |
| Q1 | 8.80 | -0.10 | 8.90 | -0.20 | 9.10 | 0.10 | 9.30 | 0.20 |
| Median | 8.90 | 0.00 | 9.10 | 0.10 | 9.30 | 0.30 | 9.40 | 0.50 |
| Q3 | 9.20 | 0.20 | 9.30 | 0.30 | 9.50 | 0.50 | 9.60 | 0.70 |
| Maximum | 9.8 | 0.6 | 10.2 | 1.0 | 10.5 | 1.0 | 10.2 | 1.1 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 8.98 | -0.02 | 9.15 | 0.12 | 9.31 | 0.31 | 9.43 | 0.44 |
| SD | 0.299 | 0.308 | 0.332 | 0.337 | 0.315 | 0.305 | 0.319 | 0.412 |
| Minimum | 8.3 | -0.9 | 8.6 | -0.6 | 8.5 | -0.3 | 8.5 | -0.4 |
| Q1 | 8.80 | -0.20 | 8.90 | -0.20 | 9.20 | 0.10 | 9.20 | 0.20 |
| Median | 9.00 | 0.00 | 9.10 | 0.10 | 9.30 | 0.30 | 9.40 | 0.45 |
| Q3 | 9.20 | 0.20 | 9.30 | 0.40 | 9.50 | 0.50 | 9.60 | 0.80 |
| Maximum | 9.8 | 0.5 | 10.1 | 1.0 | 10.0 | 1.2 | 10.3 | 1.3 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

| Visit / Statistics | Placebo (N=57) Observed Value at Visit | Placebo (N=57) Change from Baseline | TAK-385 10mg (N=48) Observed Value at Visit | TAK-385 10mg (N=48) Change from Baseline | TAK-385 20mg (N=55) Observed Value at Visit | TAK-385 20mg (N=55) Change from Baseline | TAK-385 40mg (N=54) Observed Value at Visit | TAK-385 40mg (N=54) Change from Baseline |
|---|---|---|---|---|---|---|---|---|
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 8.92 | -0.05 | 8.94 | -0.08 | 9.05 | 0.05 | 9.06 | 0.07 |
| SD | 0.374 | 0.331 | 0.346 | 0.344 | 0.296 | 0.304 | 0.257 | 0.303 |
| Minimum | 8.2 | -1.0 | 8.1 | -0.8 | 8.3 | -0.7 | 8.4 | -0.5 |
| Q1 | 8.60 | -0.30 | 8.70 | -0.20 | 8.90 | -0.10 | 8.90 | -0.20 |
| Median | 8.90 | -0.10 | 8.90 | -0.10 | 9.00 | 0.10 | 9.10 | 0.00 |
| Q3 | 9.20 | 0.20 | 9.15 | 0.00 | 9.20 | 0.30 | 9.20 | 0.20 |
| Maximum | 10.1 | 0.6 | 9.8 | 1.3 | 9.6 | 0.8 | 9.6 | 0.9 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphorus (mg/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | | | |
| N | 57 | | 48 | | 55 | | 54 | |
| Mean | 3.61 | | 3.63 | | 3.55 | | 3.57 | |
| SD | 0.398 | | 0.396 | | 0.366 | | 0.480 | |
| Minimum | 2.7 | | 2.8 | | 2.8 | | 1.9 | |
| Q1 | 3.30 | | 3.35 | | 3.30 | | 3.30 | |
| Median | 3.70 | | 3.60 | | 3.50 | | 3.55 | |
| Q3 | 3.90 | | 4.00 | | 3.90 | | 3.90 | |
| Maximum | 4.4 | | 4.4 | | 4.3 | | 4.4 | |
| Week 4 | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 3.49 | -0.12 | 3.73 | 0.10 | 3.85 | 0.31 | 3.84 | 0.28 |
| SD | 0.451 | 0.423 | 0.492 | 0.401 | 0.465 | 0.483 | 0.524 | 0.491 |
| Minimum | 2.5 | -1.3 | 2.8 | -0.7 | 2.9 | -0.6 | 2.3 | -0.9 |
| Q1 | 3.20 | -0.30 | 3.40 | -0.10 | 3.50 | 0.00 | 3.50 | 0.00 |
| Median | 3.40 | -0.10 | 3.75 | 0.00 | 3.80 | 0.30 | 3.90 | 0.30 |
| Q3 | 3.80 | 0.20 | 4.00 | 0.30 | 4.10 | 0.50 | 4.20 | 0.50 |
| Maximum | 4.6 | 0.8 | 5.1 | 1.2 | 5.1 | 2.1 | 4.8 | 1.5 |
| Week 8 | | | | | | | | |
| N | 56 | 56 | 48 | 48 | 54 | 54 | 54 | 54 |
| Mean | 3.54 | -0.06 | 3.80 | 0.17 | 3.86 | 0.30 | 4.09 | 0.52 |
| SD | 0.366 | 0.371 | 0.542 | 0.477 | 0.404 | 0.401 | 0.493 | 0.511 |
| Minimum | 2.7 | -1.0 | 2.5 | -0.8 | 2.9 | -0.7 | 2.9 | -0.9 |
| Q1 | 3.30 | -0.30 | 3.40 | -0.10 | 3.60 | 0.10 | 3.80 | 0.20 |
| Median | 3.55 | -0.05 | 3.85 | 0.10 | 3.90 | 0.30 | 4.10 | 0.50 |
| Q3 | 3.80 | 0.10 | 4.30 | 0.55 | 4.10 | 0.50 | 4.40 | 0.80 |
| Maximum | 4.2 | 0.8 | 4.8 | 1.4 | 4.9 | 1.4 | 5.3 | 1.8 |
| Week 12 | | | | | | | | |
| N | 55 | 55 | 47 | 47 | 53 | 53 | 54 | 54 |
| Mean | 3.56 | -0.06 | 3.76 | 0.13 | 3.89 | 0.34 | 4.13 | 0.56 |
| SD | 0.400 | 0.341 | 0.477 | 0.477 | 0.540 | 0.517 | 0.521 | 0.507 |
| Minimum | 2.6 | -1.1 | 2.6 | -0.7 | 2.9 | -0.9 | 2.5 | -0.3 |
| Q1 | 3.30 | -0.30 | 3.40 | -0.20 | 3.50 | 0.00 | 3.70 | 0.30 |
| Median | 3.60 | 0.00 | 3.80 | 0.10 | 3.80 | 0.30 | 4.05 | 0.50 |
| Q3 | 3.80 | 0.20 | 4.10 | 0.50 | 4.40 | 0.70 | 4.60 | 1.00 |
| Maximum | 4.5 | 0.5 | 4.9 | 1.1 | 5.2 | 1.3 | 5.1 | 1.8 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-32　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphorus (mg/dL)

| Visit / Statistics | Placebo (N=57) | | TAK-385 10mg (N=48) | | TAK-385 20mg (N=55) | | TAK-385 40mg (N=54) | |
|---|---|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Follow-up | | | | | | | | |
| N | 57 | 57 | 48 | 48 | 55 | 55 | 54 | 54 |
| Mean | 3.42 | -0.19 | 3.58 | -0.05 | 3.61 | 0.06 | 3.63 | 0.06 |
| SD | 0.572 | 0.498 | 0.511 | 0.484 | 0.413 | 0.447 | 0.449 | 0.471 |
| Minimum | 1.2 | -1.7 | 2.4 | -1.1 | 2.8 | -0.7 | 2.8 | -0.8 |
| Q1 | 3.20 | -0.60 | 3.25 | -0.40 | 3.30 | -0.20 | 3.40 | -0.30 |
| Median | 3.50 | -0.20 | 3.60 | -0.05 | 3.50 | 0.00 | 3.55 | 0.00 |
| Q3 | 3.70 | 0.20 | 3.90 | 0.25 | 3.90 | 0.30 | 4.00 | 0.40 |
| Maximum | 4.6 | 0.9 | 4.7 | 1.6 | 4.5 | 1.3 | 4.7 | 1.3 |

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 14.8 | | 14.9 | |
| SD | 10.21 | | 8.22 | |
| Minimum | 6 | | 4 | |
| Q1 | 10.0 | | 10.0 | |
| Median | 12.0 | | 12.0 | |
| Q3 | 16.0 | | 16.0 | |
| Maximum | 90 | | 49 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 19.3 | 4.5 | 17.6 | 2.7 |
| SD | 27.67 | 26.00 | 10.94 | 4.83 |
| Minimum | 8 | -61 | 5 | -7 |
| Q1 | 12.0 | 1.0 | 11.0 | 0.0 |
| Median | 15.0 | 2.0 | 14.0 | 2.0 |
| Q3 | 20.0 | 5.0 | 19.0 | 4.0 |
| Maximum | 326 | 292 | 76 | 27 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 18.9 | 4.3 | 19.1 | 4.3 |
| SD | 9.93 | 10.40 | 13.71 | 7.79 |
| Minimum | 7 | -64 | 7 | -8 |
| Q1 | 13.0 | 1.0 | 12.0 | 1.0 |
| Median | 16.0 | 3.0 | 15.0 | 3.0 |
| Q3 | 22.0 | 7.0 | 22.0 | 5.0 |
| Maximum | 63 | 49 | 116 | 67 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 19.5 | 5.0 | 21.9 | 7.0 |
| SD | 11.01 | 10.42 | 19.31 | 13.81 |
| Minimum | 6 | -54 | 8 | -8 |
| Q1 | 13.0 | 1.0 | 13.0 | 2.0 |
| Median | 16.0 | 4.0 | 16.0 | 4.0 |
| Q3 | 21.0 | 7.0 | 23.0 | 6.0 |
| Maximum | 77 | 44 | 159 | 110 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 20.0 | 5.6 | 20.3 | 6.0 |
| SD | 12.37 | 11.74 | 14.51 | 9.97 |
| Minimum | 7 | -56 | 8 | -7 |
| Q1 | 13.0 | 1.0 | 12.5 | 1.0 |
| Median | 16.0 | 4.0 | 16.0 | 4.0 |
| Q3 | 23.0 | 8.0 | 23.0 | 8.0 |
| Maximum | 111 | 59 | 107 | 76 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 22.6 | 8.1 | 20.6 | 6.3 |
| SD | 17.27 | 16.24 | 14.05 | 10.27 |
| Minimum | 5 | -38 | 7 | -10 |
| Q1 | 13.0 | 1.0 | 13.0 | 2.0 |
| Median | 17.0 | 4.0 | 16.0 | 4.0 |
| Q3 | 26.0 | 10.0 | 23.5 | 8.0 |
| Maximum | 127 | 115 | 107 | 83 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 21.0 | 6.6 | 20.7 | 6.5 |
| SD | 12.99 | 11.69 | 15.49 | 11.60 |
| Minimum | 9 | -54 | 7 | -11 |
| Q1 | 14.0 | 2.0 | 13.0 | 2.0 |
| Median | 17.0 | 5.0 | 17.0 | 4.0 |
| Q3 | 23.0 | 9.0 | 22.0 | 7.0 |
| Maximum | 98 | 46 | 132 | 108 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 18.8 | 3.8 | 22.7 | 7.8 |
| SD | 9.93 | 11.40 | 19.40 | 15.00 |
| Minimum | 8 | -65 | 7 | -8 |
| Q1 | 13.0 | 0.0 | 13.0 | 2.0 |
| Median | 16.0 | 3.0 | 17.0 | 4.0 |
| Q3 | 22.0 | 8.0 | 23.0 | 8.0 |
| Maximum | 66 | 35 | 154 | 130 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 19.0 | | 18.9 | |
| SD | 6.54 | | 4.77 | |
| Minimum | 12 | | 11 | |
| Q1 | 16.0 | | 16.0 | |
| Median | 18.0 | | 18.0 | |
| Q3 | 20.0 | | 21.0 | |
| Maximum | 80 | | 33 | |
| Week 4 | | | | |
| N | 137 | 137 | 140 | 140 |
| Mean | 21.7 | 2.7 | 20.9 | 2.0 |
| SD | 10.34 | 10.51 | 6.26 | 3.49 |
| Minimum | 13 | -52 | 9 | -8 |
| Q1 | 18.0 | 0.0 | 17.0 | 0.0 |
| Median | 20.0 | 2.0 | 19.0 | 2.0 |
| Q3 | 23.0 | 4.0 | 23.0 | 3.0 |
| Maximum | 131 | 107 | 44 | 14 |
| Week 8 | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 22.3 | 3.4 | 21.6 | 2.7 |
| SD | 7.15 | 8.29 | 7.37 | 5.31 |
| Minimum | 14 | -56 | 12 | -7 |
| Q1 | 18.0 | 1.0 | 18.0 | 0.0 |
| Median | 21.0 | 3.0 | 20.0 | 2.0 |
| Q3 | 24.0 | 5.0 | 23.0 | 4.0 |
| Maximum | 75 | 50 | 78 | 46 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 129 | 129 | 139 | 139 |
| Mean | 22.3 | 3.4 | 23.5 | 4.6 |
| SD | 5.67 | 7.24 | 9.77 | 7.53 |
| Minimum | 14 | -55 | 14 | -11 |
| Q1 | 18.0 | 1.0 | 18.0 | 1.0 |
| Median | 21.0 | 3.0 | 21.0 | 3.0 |
| Q3 | 24.0 | 5.0 | 25.0 | 5.0 |
| Maximum | 46 | 29 | 83 | 51 |
| Week 16 | | | | |
| N | 129 | 129 | 134 | 134 |
| Mean | 22.5 | 3.7 | 22.5 | 3.7 |
| SD | 5.59 | 7.12 | 7.64 | 5.36 |
| Minimum | 14 | -53 | 13 | -13 |
| Q1 | 19.0 | 1.0 | 18.0 | 1.0 |
| Median | 21.0 | 3.0 | 20.0 | 3.0 |
| Q3 | 25.0 | 6.0 | 25.0 | 5.0 |
| Maximum | 46 | 22 | 64 | 31 |
| Week 20 | | | | |
| N | 124 | 124 | 130 | 130 |
| Mean | 23.8 | 5.0 | 23.0 | 4.2 |
| SD | 9.23 | 9.33 | 7.06 | 6.31 |
| Minimum | 14 | -32 | 14 | -13 |
| Q1 | 19.0 | 1.0 | 19.0 | 1.0 |
| Median | 21.0 | 3.0 | 21.0 | 4.0 |
| Q3 | 26.0 | 6.5 | 25.0 | 6.0 |
| Maximum | 90 | 71 | 62 | 44 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 129 | 129 |
| Mean | 23.8 | 5.0 | 23.3 | 4.4 |
| SD | 8.21 | 9.00 | 8.13 | 6.73 |
| Minimum | 14 | -52 | 12 | -13 |
| Q1 | 19.0 | 1.0 | 19.0 | 1.0 |
| Median | 21.0 | 4.0 | 21.0 | 3.0 |
| Q3 | 26.0 | 6.0 | 26.0 | 6.0 |
| Maximum | 62 | 44 | 78 | 60 |
| Follow-up | | | | |
| N | 133 | 133 | 141 | 141 |
| Mean | 21.7 | 2.6 | 23.9 | 4.9 |
| SD | 5.01 | 7.34 | 9.82 | 8.43 |
| Minimum | 13 | -58 | 13 | -11 |
| Q1 | 18.0 | 0.0 | 19.0 | 1.0 |
| Median | 21.0 | 3.0 | 21.0 | 3.0 |
| Q3 | 24.0 | 5.0 | 25.0 | 6.0 |
| Maximum | 38 | 21 | 80 | 62 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Lactate dehydrogenase (LDH) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 156.9 | | 153.7 | |
| SD | 27.38 | | 22.36 | |
| Minimum | 101 | | 88 | |
| Q1 | 141.0 | | 139.0 | |
| Median | 153.0 | | 151.5 | |
| Q3 | 172.0 | | 164.0 | |
| Maximum | 273 | | 224 | |
| Week 4 | | | | |
| N | 137 | 137 | 140 | 140 |
| Mean | 167.6 | 10.4 | 162.2 | 8.5 |
| SD | 29.20 | 14.30 | 26.16 | 15.28 |
| Minimum | 107 | -33 | 96 | -49 |
| Q1 | 149.0 | 3.0 | 144.0 | 1.0 |
| Median | 165.0 | 10.0 | 159.0 | 8.0 |
| Q3 | 182.0 | 19.0 | 177.0 | 16.0 |
| Maximum | 320 | 81 | 243 | 66 |
| Week 8 | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 168.2 | 11.3 | 166.3 | 12.6 |
| SD | 26.04 | 15.97 | 27.26 | 14.73 |
| Minimum | 108 | -44 | 89 | -39 |
| Q1 | 152.0 | 1.0 | 147.0 | 3.0 |
| Median | 165.0 | 10.0 | 160.0 | 11.0 |
| Q3 | 182.0 | 22.0 | 187.0 | 21.0 |
| Maximum | 268 | 50 | 286 | 93 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Lactate dehydrogenase (LDH) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 129 | 129 | 139 | 139 |
| Mean | 168.2 | 10.8 | 167.7 | 13.8 |
| SD | 26.80 | 17.19 | 30.61 | 21.26 |
| Minimum | 110 | -43 | 93 | -49 |
| Q1 | 150.0 | -1.0 | 147.0 | 2.0 |
| Median | 165.0 | 11.0 | 163.0 | 11.0 |
| Q3 | 181.0 | 21.0 | 186.0 | 21.0 |
| Maximum | 262 | 56 | 295 | 159 |
| Week 16 | | | | |
| N | 129 | 129 | 134 | 134 |
| Mean | 166.7 | 9.3 | 164.4 | 11.2 |
| SD | 29.56 | 17.29 | 26.02 | 16.38 |
| Minimum | 104 | -54 | 90 | -56 |
| Q1 | 147.0 | -1.0 | 146.0 | 2.0 |
| Median | 163.0 | 8.0 | 161.5 | 10.5 |
| Q3 | 180.0 | 22.0 | 179.0 | 21.0 |
| Maximum | 312 | 54 | 251 | 57 |
| Week 20 | | | | |
| N | 124 | 124 | 130 | 130 |
| Mean | 168.8 | 11.7 | 166.5 | 13.3 |
| SD | 26.85 | 16.88 | 24.64 | 14.68 |
| Minimum | 106 | -38 | 91 | -43 |
| Q1 | 153.0 | 0.5 | 149.0 | 4.0 |
| Median | 165.0 | 12.5 | 161.0 | 12.0 |
| Q3 | 183.0 | 22.0 | 181.0 | 22.0 |
| Maximum | 283 | 63 | 231 | 50 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Lactate dehydrogenase (LDH) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 129 | 129 |
| Mean | 170.3 | 13.0 | 165.8 | 12.3 |
| SD | 28.04 | 17.47 | 24.66 | 15.50 |
| Minimum | 110 | -53 | 104 | -49 |
| Q1 | 151.0 | 2.0 | 148.0 | 3.0 |
| Median | 168.0 | 14.0 | 162.0 | 13.0 |
| Q3 | 187.0 | 24.0 | 180.0 | 21.0 |
| Maximum | 256 | 66 | 228 | 64 |
| Follow-up | | | | |
| N | 133 | 133 | 141 | 141 |
| Mean | 162.1 | 4.8 | 166.5 | 12.8 |
| SD | 28.04 | 15.80 | 27.20 | 17.18 |
| Minimum | 104 | -54 | 96 | -38 |
| Q1 | 146.0 | -5.0 | 147.0 | 4.0 |
| Median | 160.0 | 4.0 | 161.0 | 12.0 |
| Q3 | 176.0 | 13.0 | 182.0 | 20.0 |
| Maximum | 250 | 48 | 264 | 99 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Gamma glutamyl transferase (GGT) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 19.6 | | 17.9 | |
| SD | 22.63 | | 14.40 | |
| Minimum | 5 | | 4 | |
| Q1 | 10.0 | | 10.0 | |
| Median | 13.0 | | 14.0 | |
| Q3 | 20.0 | | 21.0 | |
| Maximum | 219 | | 135 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 24.4 | 4.8 | 19.7 | 1.8 |
| SD | 34.61 | 16.63 | 15.64 | 5.21 |
| Minimum | 6 | -29 | 6 | -14 |
| Q1 | 12.0 | 0.0 | 10.0 | -1.0 |
| Median | 16.0 | 2.0 | 14.0 | 1.0 |
| Q3 | 23.0 | 4.0 | 24.0 | 3.0 |
| Maximum | 372 | 153 | 134 | 22 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 26.2 | 6.9 | 22.5 | 4.7 |
| SD | 34.96 | 17.70 | 19.08 | 10.15 |
| Minimum | 6 | -40 | 6 | -13 |
| Q1 | 12.0 | 1.0 | 11.0 | 1.0 |
| Median | 17.0 | 3.0 | 16.0 | 2.0 |
| Q3 | 25.0 | 7.0 | 26.0 | 5.0 |
| Maximum | 354 | 135 | 122 | 64 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Gamma glutamyl transferase (GGT) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 27.7 | 8.2 | 25.1 | 7.1 |
| SD | 38.00 | 18.00 | 23.50 | 15.61 |
| Minimum | 8 | -8 | 5 | -13 |
| Q1 | 13.0 | 2.0 | 11.0 | 1.0 |
| Median | 18.0 | 4.5 | 17.0 | 3.0 |
| Q3 | 27.0 | 9.0 | 28.0 | 7.0 |
| Maximum | 390 | 171 | 144 | 118 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 27.8 | 8.3 | 23.9 | 6.4 |
| SD | 39.17 | 20.09 | 21.20 | 15.04 |
| Minimum | 6 | -30 | 5 | -60 |
| Q1 | 13.0 | 1.0 | 12.0 | 1.0 |
| Median | 18.0 | 4.0 | 17.0 | 3.0 |
| Q3 | 29.0 | 10.0 | 27.0 | 7.0 |
| Maximum | 404 | 185 | 164 | 107 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 32.1 | 12.5 | 24.3 | 6.7 |
| SD | 44.74 | 28.85 | 19.64 | 13.33 |
| Minimum | 6 | -11 | 6 | -51 |
| Q1 | 13.0 | 2.0 | 12.0 | 1.0 |
| Median | 18.0 | 5.0 | 17.0 | 3.0 |
| Q3 | 29.0 | 10.0 | 30.0 | 8.5 |
| Maximum | 326 | 215 | 120 | 85 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Gamma glutamyl transferase (GGT) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 29.9 | 10.2 | 25.4 | 7.7 |
| SD | 43.20 | 21.93 | 22.82 | 15.32 |
| Minimum | 7 | -9 | 5 | -27 |
| Q1 | 13.0 | 2.0 | 12.0 | 1.0 |
| Median | 18.0 | 4.0 | 18.0 | 3.0 |
| Q3 | 29.0 | 10.0 | 27.0 | 8.0 |
| Maximum | 416 | 197 | 135 | 109 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 26.6 | 6.9 | 25.2 | 7.3 |
| SD | 31.15 | 14.61 | 21.59 | 14.69 |
| Minimum | 8 | -16 | 6 | -42 |
| Q1 | 12.0 | 1.0 | 12.0 | 1.0 |
| Median | 17.0 | 2.0 | 18.0 | 3.0 |
| Q3 | 26.0 | 7.0 | 29.0 | 8.0 |
| Maximum | 270 | 123 | 133 | 107 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 4.26 | | 4.27 | |
| SD | 0.236 | | 0.194 | |
| Minimum | 3.4 | | 3.8 | |
| Q1 | 4.10 | | 4.10 | |
| Median | 4.30 | | 4.20 | |
| Q3 | 4.40 | | 4.40 | |
| Maximum | 4.8 | | 4.8 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 4.47 | 0.21 | 4.44 | 0.17 |
| SD | 0.190 | 0.224 | 0.213 | 0.212 |
| Minimum | 4.0 | -0.3 | 3.9 | -0.4 |
| Q1 | 4.30 | 0.10 | 4.30 | 0.00 |
| Median | 4.50 | 0.20 | 4.40 | 0.20 |
| Q3 | 4.60 | 0.40 | 4.60 | 0.30 |
| Maximum | 5.0 | 1.0 | 5.2 | 0.8 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 4.48 | 0.21 | 4.49 | 0.23 |
| SD | 0.200 | 0.257 | 0.207 | 0.211 |
| Minimum | 4.0 | -0.4 | 4.0 | -0.3 |
| Q1 | 4.30 | 0.10 | 4.40 | 0.10 |
| Median | 4.50 | 0.20 | 4.50 | 0.20 |
| Q3 | 4.60 | 0.40 | 4.60 | 0.30 |
| Maximum | 4.9 | 1.1 | 5.1 | 0.8 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 4.51 | 0.25 | 4.49 | 0.23 |
| SD | 0.208 | 0.235 | 0.217 | 0.210 |
| Minimum | 4.1 | -0.3 | 3.9 | -0.3 |
| Q1 | 4.40 | 0.10 | 4.30 | 0.10 |
| Median | 4.50 | 0.20 | 4.50 | 0.20 |
| Q3 | 4.70 | 0.40 | 4.60 | 0.40 |
| Maximum | 5.1 | 0.9 | 5.0 | 0.8 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 4.48 | 0.22 | 4.49 | 0.22 |
| SD | 0.215 | 0.241 | 0.199 | 0.215 |
| Minimum | 3.6 | -0.4 | 4.1 | -0.4 |
| Q1 | 4.40 | 0.10 | 4.30 | 0.10 |
| Median | 4.50 | 0.20 | 4.50 | 0.20 |
| Q3 | 4.60 | 0.40 | 4.60 | 0.30 |
| Maximum | 5.1 | 1.1 | 5.0 | 0.8 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 4.47 | 0.20 | 4.50 | 0.23 |
| SD | 0.201 | 0.240 | 0.209 | 0.205 |
| Minimum | 4.0 | -0.5 | 3.5 | -0.4 |
| Q1 | 4.30 | 0.00 | 4.40 | 0.10 |
| Median | 4.50 | 0.20 | 4.50 | 0.20 |
| Q3 | 4.60 | 0.40 | 4.60 | 0.30 |
| Maximum | 5.0 | 1.1 | 5.1 | 0.8 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 4.49 | 0.23 | 4.50 | 0.24 |
| SD | 0.221 | 0.245 | 0.211 | 0.200 |
| Minimum | 4.0 | -0.3 | 4.1 | -0.3 |
| Q1 | 4.30 | 0.00 | 4.40 | 0.10 |
| Median | 4.50 | 0.20 | 4.50 | 0.20 |
| Q3 | 4.60 | 0.40 | 4.60 | 0.40 |
| Maximum | 5.1 | 1.2 | 5.1 | 0.8 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 4.34 | 0.08 | 4.48 | 0.21 |
| SD | 0.204 | 0.234 | 0.199 | 0.221 |
| Minimum | 3.9 | -0.9 | 4.1 | -0.4 |
| Q1 | 4.20 | -0.10 | 4.40 | 0.10 |
| Median | 4.40 | 0.10 | 4.50 | 0.20 |
| Q3 | 4.50 | 0.20 | 4.60 | 0.30 |
| Maximum | 4.9 | 0.8 | 5.0 | 0.9 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline phosphatase (ALP) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 166.9 | | 166.7 | |
| SD | 45.96 | | 48.38 | |
| Minimum | 70 | | 60 | |
| Q1 | 137.0 | | 136.0 | |
| Median | 157.5 | | 159.0 | |
| Q3 | 192.0 | | 190.0 | |
| Maximum | 385 | | 393 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 183.4 | 16.6 | 176.4 | 9.8 |
| SD | 55.13 | 27.49 | 49.42 | 26.38 |
| Minimum | 79 | -77 | 65 | -166 |
| Q1 | 148.0 | 3.0 | 145.0 | -1.0 |
| Median | 175.5 | 14.0 | 169.5 | 9.0 |
| Q3 | 207.0 | 22.0 | 202.0 | 22.0 |
| Maximum | 476 | 211 | 372 | 109 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 188.6 | 21.3 | 185.1 | 18.4 |
| SD | 53.35 | 27.23 | 50.26 | 23.03 |
| Minimum | 80 | -43 | 71 | -88 |
| Q1 | 152.0 | 6.0 | 152.0 | 5.0 |
| Median | 180.0 | 19.0 | 179.0 | 18.0 |
| Q3 | 213.0 | 34.0 | 211.0 | 29.0 |
| Maximum | 422 | 159 | 343 | 89 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline phosphatase (ALP) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 196.9 | 29.4 | 196.1 | 28.7 |
| SD | 55.18 | 31.48 | 51.43 | 29.75 |
| Minimum | 76 | -39 | 92 | -132 |
| Q1 | 159.0 | 12.0 | 161.0 | 10.0 |
| Median | 189.0 | 27.5 | 190.0 | 28.0 |
| Q3 | 227.0 | 45.0 | 224.0 | 46.0 |
| Maximum | 459 | 206 | 358 | 118 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 204.8 | 37.1 | 200.9 | 34.7 |
| SD | 53.21 | 30.66 | 52.04 | 28.09 |
| Minimum | 96 | -54 | 97 | -101 |
| Q1 | 167.0 | 22.0 | 167.5 | 19.0 |
| Median | 199.0 | 34.0 | 193.5 | 32.0 |
| Q3 | 232.0 | 49.0 | 229.5 | 49.0 |
| Maximum | 410 | 196 | 371 | 141 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 218.6 | 50.3 | 206.9 | 41.2 |
| SD | 62.81 | 41.10 | 50.35 | 30.25 |
| Minimum | 87 | -39 | 119 | -105 |
| Q1 | 176.0 | 28.0 | 174.5 | 24.0 |
| Median | 209.0 | 46.0 | 197.5 | 40.0 |
| Q3 | 254.0 | 66.0 | 237.0 | 58.5 |
| Maximum | 475 | 202 | 346 | 113 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline phosphatase (ALP) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 220.6 | 52.0 | 214.8 | 49.1 |
| SD | 62.64 | 32.52 | 53.16 | 31.21 |
| Minimum | 79 | -29 | 121 | -74 |
| Q1 | 175.0 | 30.0 | 176.0 | 30.0 |
| Median | 214.0 | 51.5 | 208.0 | 50.0 |
| Q3 | 260.0 | 73.0 | 244.0 | 67.0 |
| Maximum | 532 | 147 | 363 | 140 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 217.2 | 49.7 | 224.2 | 57.4 |
| SD | 62.61 | 40.16 | 55.33 | 36.10 |
| Minimum | 70 | -45 | 63 | -92 |
| Q1 | 175.0 | 22.0 | 186.0 | 37.0 |
| Median | 208.0 | 48.0 | 216.0 | 53.0 |
| Q3 | 249.0 | 69.0 | 266.0 | 78.0 |
| Maximum | 461 | 211 | 397 | 186 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bilirubin (Total bilirubin) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 0.58 | | 0.57 | |
| SD | 0.241 | | 0.207 | |
| Minimum | 0.2 | | 0.2 | |
| Q1 | 0.40 | | 0.40 | |
| Median | 0.50 | | 0.50 | |
| Q3 | 0.70 | | 0.70 | |
| Maximum | 1.7 | | 1.2 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 0.63 | 0.05 | 0.59 | 0.01 |
| SD | 0.267 | 0.200 | 0.204 | 0.169 |
| Minimum | 0.3 | -0.4 | 0.2 | -0.4 |
| Q1 | 0.40 | -0.10 | 0.40 | -0.10 |
| Median | 0.60 | 0.00 | 0.50 | 0.00 |
| Q3 | 0.70 | 0.20 | 0.70 | 0.10 |
| Maximum | 1.6 | 0.8 | 1.3 | 0.6 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 0.66 | 0.08 | 0.63 | 0.05 |
| SD | 0.280 | 0.203 | 0.221 | 0.210 |
| Minimum | 0.2 | -0.6 | 0.3 | -0.7 |
| Q1 | 0.50 | -0.10 | 0.50 | -0.10 |
| Median | 0.60 | 0.10 | 0.60 | 0.00 |
| Q3 | 0.80 | 0.20 | 0.70 | 0.20 |
| Maximum | 1.7 | 0.8 | 1.3 | 0.7 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bilirubin (Total bilirubin) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 0.67 | 0.10 | 0.63 | 0.06 |
| SD | 0.276 | 0.205 | 0.245 | 0.197 |
| Minimum | 0.2 | -0.7 | 0.3 | -0.5 |
| Q1 | 0.50 | 0.00 | 0.50 | -0.10 |
| Median | 0.60 | 0.10 | 0.60 | 0.00 |
| Q3 | 0.80 | 0.20 | 0.70 | 0.20 |
| Maximum | 1.9 | 0.8 | 1.6 | 0.7 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 0.65 | 0.08 | 0.67 | 0.10 |
| SD | 0.277 | 0.235 | 0.264 | 0.236 |
| Minimum | 0.3 | -0.6 | 0.2 | -0.3 |
| Q1 | 0.50 | 0.00 | 0.50 | 0.00 |
| Median | 0.60 | 0.10 | 0.60 | 0.10 |
| Q3 | 0.80 | 0.20 | 0.80 | 0.20 |
| Maximum | 1.6 | 1.1 | 1.8 | 1.5 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 0.62 | 0.05 | 0.65 | 0.08 |
| SD | 0.266 | 0.265 | 0.242 | 0.237 |
| Minimum | 0.2 | -0.8 | 0.3 | -0.6 |
| Q1 | 0.40 | -0.10 | 0.50 | -0.10 |
| Median | 0.60 | 0.00 | 0.60 | 0.10 |
| Q3 | 0.70 | 0.20 | 0.80 | 0.20 |
| Maximum | 1.8 | 1.0 | 1.5 | 0.8 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bilirubin (Total bilirubin) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 0.61 | 0.05 | 0.65 | 0.08 |
| SD | 0.249 | 0.229 | 0.255 | 0.224 |
| Minimum | 0.2 | -0.6 | 0.2 | -0.3 |
| Q1 | 0.50 | -0.10 | 0.50 | -0.10 |
| Median | 0.60 | 0.00 | 0.60 | 0.00 |
| Q3 | 0.70 | 0.20 | 0.80 | 0.20 |
| Maximum | 1.9 | 0.9 | 1.6 | 0.8 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 0.64 | 0.06 | 0.62 | 0.04 |
| SD | 0.255 | 0.210 | 0.222 | 0.197 |
| Minimum | 0.2 | -0.9 | 0.2 | -0.5 |
| Q1 | 0.50 | -0.10 | 0.50 | -0.10 |
| Median | 0.60 | 0.00 | 0.60 | 0.00 |
| Q3 | 0.80 | 0.20 | 0.70 | 0.20 |
| Maximum | 1.5 | 0.6 | 1.4 | 0.7 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Protein (Total protein) (g/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 6.89 | | 6.88 | |
| SD | 0.395 | | 0.402 | |
| Minimum | 5.3 | | 5.9 | |
| Q1 | 6.60 | | 6.60 | |
| Median | 6.90 | | 6.90 | |
| Q3 | 7.10 | | 7.10 | |
| Maximum | 8.0 | | 8.0 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 7.24 | 0.36 | 7.17 | 0.29 |
| SD | 0.328 | 0.324 | 0.394 | 0.325 |
| Minimum | 6.4 | -0.5 | 6.2 | -0.5 |
| Q1 | 7.00 | 0.10 | 6.90 | 0.10 |
| Median | 7.20 | 0.40 | 7.20 | 0.30 |
| Q3 | 7.50 | 0.60 | 7.40 | 0.50 |
| Maximum | 8.2 | 1.4 | 8.5 | 1.2 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 7.30 | 0.41 | 7.28 | 0.40 |
| SD | 0.340 | 0.407 | 0.379 | 0.319 |
| Minimum | 6.5 | -0.8 | 6.5 | -0.3 |
| Q1 | 7.00 | 0.20 | 7.00 | 0.20 |
| Median | 7.30 | 0.40 | 7.30 | 0.40 |
| Q3 | 7.60 | 0.70 | 7.50 | 0.60 |
| Maximum | 8.0 | 1.8 | 8.7 | 1.4 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Protein (Total protein) (g/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 7.31 | 0.43 | 7.28 | 0.40 |
| SD | 0.368 | 0.410 | 0.413 | 0.334 |
| Minimum | 6.3 | -0.6 | 6.2 | -0.5 |
| Q1 | 7.10 | 0.10 | 7.00 | 0.20 |
| Median | 7.30 | 0.45 | 7.30 | 0.40 |
| Q3 | 7.50 | 0.70 | 7.50 | 0.60 |
| Maximum | 8.5 | 1.3 | 8.2 | 1.4 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 7.26 | 0.37 | 7.25 | 0.37 |
| SD | 0.347 | 0.406 | 0.368 | 0.335 |
| Minimum | 6.4 | -0.6 | 6.5 | -0.3 |
| Q1 | 7.00 | 0.10 | 7.00 | 0.10 |
| Median | 7.20 | 0.40 | 7.20 | 0.30 |
| Q3 | 7.50 | 0.60 | 7.50 | 0.60 |
| Maximum | 8.5 | 1.6 | 8.4 | 1.4 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 7.25 | 0.35 | 7.27 | 0.38 |
| SD | 0.348 | 0.393 | 0.366 | 0.303 |
| Minimum | 6.5 | -0.7 | 6.6 | -0.4 |
| Q1 | 7.00 | 0.10 | 7.00 | 0.20 |
| Median | 7.20 | 0.30 | 7.20 | 0.30 |
| Q3 | 7.40 | 0.60 | 7.50 | 0.60 |
| Maximum | 8.5 | 1.5 | 8.3 | 1.2 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Protein (Total protein) (g/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 7.23 | 0.34 | 7.27 | 0.38 |
| SD | 0.361 | 0.357 | 0.400 | 0.335 |
| Minimum | 6.5 | -0.5 | 6.4 | -0.4 |
| Q1 | 7.00 | 0.00 | 7.00 | 0.20 |
| Median | 7.20 | 0.40 | 7.20 | 0.40 |
| Q3 | 7.50 | 0.60 | 7.50 | 0.60 |
| Maximum | 8.2 | 1.4 | 8.7 | 1.2 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 6.99 | 0.10 | 7.19 | 0.31 |
| SD | 0.313 | 0.367 | 0.392 | 0.370 |
| Minimum | 6.0 | -0.9 | 6.2 | -0.8 |
| Q1 | 6.80 | -0.10 | 6.90 | 0.10 |
| Median | 7.00 | 0.10 | 7.20 | 0.30 |
| Q3 | 7.20 | 0.30 | 7.40 | 0.50 |
| Maximum | 7.8 | 1.6 | 8.8 | 1.5 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Cholesterol (Total cholesterol) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 187.4 | | 186.1 | |
| SD | 28.51 | | 25.70 | |
| Minimum | 130 | | 129 | |
| Q1 | 168.0 | | 167.0 | |
| Median | 186.5 | | 183.0 | |
| Q3 | 204.0 | | 204.0 | |
| Maximum | 260 | | 270 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 207.6 | 20.2 | 206.5 | 20.4 |
| SD | 31.15 | 18.88 | 32.69 | 19.25 |
| Minimum | 125 | -23 | 131 | -25 |
| Q1 | 188.0 | 8.0 | 183.0 | 8.0 |
| Median | 207.0 | 20.0 | 205.0 | 19.0 |
| Q3 | 229.0 | 29.0 | 227.0 | 31.0 |
| Maximum | 300 | 111 | 340 | 90 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 212.5 | 25.4 | 207.7 | 21.6 |
| SD | 33.45 | 20.59 | 31.07 | 20.22 |
| Minimum | 134 | -29 | 148 | -26 |
| Q1 | 188.0 | 12.0 | 184.0 | 9.0 |
| Median | 210.0 | 25.0 | 204.0 | 22.0 |
| Q3 | 236.0 | 38.0 | 229.0 | 35.0 |
| Maximum | 305 | 71 | 334 | 98 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Cholesterol (Total cholesterol) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 211.9 | 25.0 | 211.5 | 25.1 |
| SD | 33.70 | 20.53 | 36.17 | 21.79 |
| Minimum | 128 | -24 | 152 | -25 |
| Q1 | 188.0 | 10.0 | 185.0 | 10.0 |
| Median | 211.5 | 25.0 | 205.0 | 25.0 |
| Q3 | 233.0 | 38.0 | 235.0 | 37.0 |
| Maximum | 287 | 92 | 334 | 84 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 213.9 | 27.1 | 210.5 | 24.5 |
| SD | 36.11 | 25.79 | 32.76 | 20.79 |
| Minimum | 116 | -38 | 154 | -21 |
| Q1 | 190.0 | 12.0 | 188.0 | 12.0 |
| Median | 212.0 | 25.0 | 210.0 | 22.0 |
| Q3 | 236.0 | 40.0 | 228.5 | 36.5 |
| Maximum | 338 | 139 | 362 | 112 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 212.1 | 24.6 | 211.5 | 25.9 |
| SD | 31.87 | 23.15 | 29.80 | 20.17 |
| Minimum | 141 | -25 | 141 | -22 |
| Q1 | 188.0 | 10.0 | 191.0 | 11.5 |
| Median | 210.5 | 21.0 | 205.0 | 23.0 |
| Q3 | 236.0 | 38.0 | 232.5 | 39.0 |
| Maximum | 310 | 127 | 307 | 83 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Cholesterol (Total cholesterol) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 214.3 | 27.1 | 213.6 | 28.0 |
| SD | 36.41 | 23.42 | 32.19 | 21.34 |
| Minimum | 141 | -23 | 149 | -44 |
| Q1 | 187.0 | 13.0 | 190.0 | 15.0 |
| Median | 214.5 | 27.5 | 207.0 | 27.0 |
| Q3 | 237.0 | 38.0 | 240.0 | 42.0 |
| Maximum | 330 | 104 | 345 | 93 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 203.4 | 15.3 | 214.3 | 28.0 |
| SD | 32.04 | 22.22 | 32.03 | 23.60 |
| Minimum | 127 | -33 | 150 | -26 |
| Q1 | 181.0 | -1.0 | 192.0 | 13.0 |
| Median | 202.0 | 14.0 | 212.0 | 26.0 |
| Q3 | 225.0 | 32.0 | 229.0 | 42.0 |
| Maximum | 277 | 96 | 336 | 101 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: High density lipoprotein (HDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 63.1 | | 63.8 | |
| SD | 15.10 | | 15.76 | |
| Minimum | 31 | | 29 | |
| Q1 | 52.0 | | 53.0 | |
| Median | 62.0 | | 63.0 | |
| Q3 | 74.0 | | 74.0 | |
| Maximum | 105 | | 133 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 67.7 | 4.6 | 70.0 | 6.2 |
| SD | 17.18 | 6.92 | 18.26 | 7.42 |
| Minimum | 34 | -14 | 29 | -15 |
| Q1 | 56.0 | 1.0 | 56.0 | 1.0 |
| Median | 66.0 | 4.0 | 68.5 | 5.0 |
| Q3 | 77.0 | 8.0 | 82.0 | 10.0 |
| Maximum | 126 | 23 | 140 | 26 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 67.5 | 4.4 | 68.6 | 4.8 |
| SD | 17.04 | 7.70 | 16.90 | 7.28 |
| Minimum | 34 | -20 | 33 | -10 |
| Q1 | 56.0 | -1.0 | 56.0 | 0.0 |
| Median | 65.0 | 5.0 | 68.0 | 5.0 |
| Q3 | 77.0 | 10.0 | 78.0 | 9.0 |
| Maximum | 128 | 23 | 135 | 28 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: High density lipoprotein (HDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 68.4 | 5.6 | 69.3 | 5.5 |
| SD | 17.79 | 8.23 | 17.60 | 8.04 |
| Minimum | 31 | -21 | 31 | -25 |
| Q1 | 56.0 | 0.0 | 57.0 | 0.0 |
| Median | 67.5 | 4.0 | 67.0 | 6.0 |
| Q3 | 77.0 | 10.0 | 81.0 | 11.0 |
| Maximum | 129 | 31 | 145 | 25 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 67.8 | 5.1 | 71.1 | 6.6 |
| SD | 17.23 | 10.05 | 17.12 | 7.91 |
| Minimum | 37 | -29 | 42 | -16 |
| Q1 | 56.0 | 0.0 | 58.0 | 1.0 |
| Median | 67.0 | 4.0 | 70.0 | 6.0 |
| Q3 | 77.0 | 12.0 | 82.0 | 10.5 |
| Maximum | 124 | 36 | 136 | 30 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 68.0 | 5.2 | 71.5 | 7.0 |
| SD | 16.13 | 8.96 | 16.86 | 7.81 |
| Minimum | 35 | -22 | 38 | -12 |
| Q1 | 56.0 | 0.0 | 59.5 | 2.0 |
| Median | 67.0 | 5.0 | 70.5 | 7.0 |
| Q3 | 79.0 | 10.0 | 82.5 | 12.0 |
| Maximum | 123 | 30 | 139 | 25 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: High density lipoprotein (HDL) cholesterol (mg/dL)

| | TAK-385 40mg (N=138) | | Leuprorelin (N=142) | |
|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 69.2 | 6.4 | 72.7 | 8.1 |
| SD | 16.62 | 8.48 | 18.12 | 8.52 |
| Minimum | 35 | -20 | 34 | -23 |
| Q1 | 58.0 | 2.0 | 61.0 | 2.0 |
| Median | 69.0 | 6.0 | 72.0 | 8.0 |
| Q3 | 79.0 | 11.0 | 84.0 | 14.0 |
| Maximum | 126 | 28 | 148 | 38 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 67.2 | 4.3 | 72.0 | 8.1 |
| SD | 15.24 | 9.00 | 18.49 | 8.76 |
| Minimum | 35 | -18 | 29 | -17 |
| Q1 | 57.0 | -2.0 | 59.0 | 2.0 |
| Median | 67.0 | 5.0 | 71.0 | 7.0 |
| Q3 | 78.0 | 12.0 | 82.0 | 14.0 |
| Maximum | 115 | 27 | 140 | 28 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Low density lipoprotein (LDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 109.8 | | 106.3 | |
| SD | 25.16 | | 24.96 | |
| Minimum | 55 | | 45 | |
| Q1 | 92.0 | | 88.0 | |
| Median | 108.0 | | 103.0 | |
| Q3 | 127.0 | | 124.0 | |
| Maximum | 179 | | 191 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 124.0 | 14.2 | 117.6 | 11.3 |
| SD | 29.17 | 16.40 | 31.00 | 16.68 |
| Minimum | 67 | -17 | 36 | -34 |
| Q1 | 103.0 | 3.0 | 97.0 | 1.0 |
| Median | 121.5 | 12.0 | 112.5 | 8.0 |
| Q3 | 144.0 | 25.0 | 134.0 | 20.0 |
| Maximum | 216 | 87 | 209 | 78 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 126.9 | 17.2 | 120.1 | 13.8 |
| SD | 31.41 | 16.84 | 30.61 | 17.75 |
| Minimum | 59 | -25 | 51 | -26 |
| Q1 | 104.0 | 6.0 | 100.0 | 3.0 |
| Median | 125.0 | 18.0 | 114.0 | 13.0 |
| Q3 | 146.0 | 27.0 | 140.0 | 23.0 |
| Maximum | 203 | 58 | 219 | 88 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Low density lipoprotein (LDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 126.0 | 16.4 | 120.8 | 14.3 |
| SD | 30.96 | 17.55 | 33.76 | 18.83 |
| Minimum | 58 | -21 | 61 | -29 |
| Q1 | 103.0 | 5.0 | 92.0 | 0.0 |
| Median | 126.0 | 14.0 | 115.0 | 13.0 |
| Q3 | 144.0 | 27.0 | 143.0 | 26.0 |
| Maximum | 202 | 74 | 236 | 71 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 125.9 | 16.4 | 119.8 | 14.0 |
| SD | 32.68 | 22.52 | 31.96 | 18.93 |
| Minimum | 50 | -32 | 68 | -21 |
| Q1 | 102.0 | 3.0 | 97.5 | 1.0 |
| Median | 126.0 | 14.0 | 114.5 | 12.0 |
| Q3 | 146.0 | 28.0 | 139.5 | 23.5 |
| Maximum | 236 | 116 | 222 | 91 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 124.8 | 14.7 | 120.5 | 14.7 |
| SD | 30.06 | 18.63 | 30.21 | 17.52 |
| Minimum | 60 | -29 | 69 | -35 |
| Q1 | 101.0 | 3.0 | 99.0 | 3.5 |
| Median | 127.0 | 13.5 | 112.5 | 13.0 |
| Q3 | 144.0 | 24.0 | 142.0 | 24.0 |
| Maximum | 220 | 101 | 215 | 67 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Low density lipoprotein (LDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 125.9 | 16.0 | 121.5 | 15.9 |
| SD | 34.51 | 20.32 | 32.37 | 18.92 |
| Minimum | 61 | -31 | 63 | -33 |
| Q1 | 98.0 | 5.0 | 100.0 | 4.0 |
| Median | 124.0 | 14.0 | 114.0 | 14.0 |
| Q3 | 150.0 | 27.0 | 144.0 | 26.0 |
| Maximum | 248 | 97 | 242 | 89 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 118.9 | 8.3 | 121.6 | 15.1 |
| SD | 28.56 | 18.24 | 32.20 | 19.04 |
| Minimum | 44 | -30 | 56 | -29 |
| Q1 | 99.0 | -4.0 | 99.0 | 3.0 |
| Median | 119.0 | 5.0 | 118.0 | 13.0 |
| Q3 | 136.0 | 23.0 | 142.0 | 27.0 |
| Maximum | 193 | 62 | 218 | 87 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 84.2 | | 101.8 | |
| SD | 42.41 | | 103.10 | |
| Minimum | 25 | | 26 | |
| Q1 | 55.0 | | 51.0 | |
| Median | 70.5 | | 72.5 | |
| Q3 | 100.0 | | 116.0 | |
| Maximum | 234 | | 995 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 97.5 | 13.4 | 117.8 | 16.1 |
| SD | 54.27 | 33.86 | 135.56 | 58.95 |
| Minimum | 26 | -102 | 27 | -158 |
| Q1 | 58.0 | -6.0 | 53.0 | -11.0 |
| Median | 84.0 | 9.0 | 83.0 | 7.5 |
| Q3 | 117.0 | 26.0 | 128.0 | 33.0 |
| Maximum | 345 | 160 | 1365 | 370 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 108.7 | 24.9 | 111.5 | 9.7 |
| SD | 68.76 | 51.37 | 79.40 | 87.57 |
| Minimum | 32 | -93 | 26 | -722 |
| Q1 | 62.0 | -3.0 | 61.0 | -9.0 |
| Median | 87.0 | 13.0 | 88.0 | 12.0 |
| Q3 | 133.0 | 41.0 | 131.0 | 32.0 |
| Maximum | 370 | 259 | 595 | 438 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 104.0 | 19.5 | 123.6 | 21.5 |
| SD | 61.54 | 45.51 | 118.33 | 81.00 |
| Minimum | 25 | -79 | 28 | -225 |
| Q1 | 58.0 | -9.0 | 59.0 | -10.0 |
| Median | 86.5 | 10.0 | 89.0 | 11.0 |
| Q3 | 140.0 | 40.0 | 139.0 | 35.0 |
| Maximum | 353 | 235 | 911 | 549 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 110.4 | 25.7 | 107.6 | 7.7 |
| SD | 75.57 | 59.14 | 71.69 | 86.36 |
| Minimum | 26 | -117 | 25 | -719 |
| Q1 | 62.0 | -8.0 | 60.0 | -7.0 |
| Median | 91.0 | 15.0 | 87.0 | 8.0 |
| Q3 | 126.0 | 38.0 | 127.5 | 36.0 |
| Maximum | 526 | 394 | 426 | 294 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 102.7 | 17.4 | 104.9 | 6.5 |
| SD | 60.93 | 42.17 | 76.40 | 85.18 |
| Minimum | 30 | -84 | 24 | -632 |
| Q1 | 64.0 | -7.0 | 57.0 | -10.0 |
| Median | 86.0 | 15.0 | 81.0 | 5.0 |
| Q3 | 123.0 | 33.0 | 124.5 | 28.0 |
| Maximum | 378 | 267 | 493 | 361 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 101.8 | 16.6 | 104.9 | 6.3 |
| SD | 57.04 | 44.90 | 70.27 | 85.38 |
| Minimum | 29 | -73 | 25 | -679 |
| Q1 | 60.0 | -12.0 | 61.0 | -8.0 |
| Median | 86.0 | 10.5 | 88.0 | 6.0 |
| Q3 | 136.0 | 30.0 | 127.0 | 31.0 |
| Maximum | 384 | 266 | 470 | 354 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 90.1 | 5.9 | 113.3 | 11.3 |
| SD | 48.73 | 36.83 | 90.84 | 87.60 |
| Minimum | 32 | -72 | 25 | -656 |
| Q1 | 55.0 | -15.0 | 59.0 | -6.0 |
| Median | 79.0 | -1.0 | 82.0 | 11.0 |
| Q3 | 108.0 | 21.0 | 128.0 | 32.0 |
| Maximum | 264 | 169 | 606 | 502 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 92.7 | | 94.9 | |
| SD | 7.93 | | 12.89 | |
| Minimum | 77 | | 75 | |
| Q1 | 87.0 | | 88.0 | |
| Median | 92.0 | | 92.0 | |
| Q3 | 97.0 | | 98.0 | |
| Maximum | 128 | | 177 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 95.3 | 2.6 | 96.1 | 1.2 |
| SD | 12.34 | 10.68 | 14.77 | 14.57 |
| Minimum | 68 | -23 | 65 | -78 |
| Q1 | 89.0 | -3.0 | 89.0 | -2.0 |
| Median | 93.0 | 1.0 | 93.5 | 1.0 |
| Q3 | 99.0 | 6.0 | 98.0 | 4.0 |
| Maximum | 163 | 64 | 181 | 67 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 95.1 | 2.5 | 96.8 | 1.8 |
| SD | 9.62 | 10.49 | 9.68 | 12.25 |
| Minimum | 78 | -35 | 70 | -66 |
| Q1 | 89.0 | -4.0 | 91.0 | -2.0 |
| Median | 95.0 | 2.0 | 95.0 | 3.0 |
| Q3 | 99.0 | 7.0 | 100.0 | 6.0 |
| Maximum | 137 | 41 | 131 | 42 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 95.7 | 2.9 | 96.2 | 1.2 |
| SD | 9.93 | 10.48 | 13.12 | 14.18 |
| Minimum | 78 | -27 | 62 | -87 |
| Q1 | 89.0 | -3.0 | 90.0 | -2.0 |
| Median | 94.5 | 3.0 | 94.0 | 1.0 |
| Q3 | 100.0 | 8.0 | 100.0 | 6.0 |
| Maximum | 140 | 49 | 195 | 61 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 95.9 | 3.1 | 97.4 | 2.6 |
| SD | 8.74 | 8.98 | 10.83 | 12.55 |
| Minimum | 76 | -25 | 69 | -84 |
| Q1 | 91.0 | -1.0 | 91.0 | -1.0 |
| Median | 96.0 | 3.0 | 96.0 | 3.0 |
| Q3 | 100.0 | 8.0 | 102.0 | 7.0 |
| Maximum | 137 | 38 | 144 | 43 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 97.6 | 4.6 | 97.6 | 2.5 |
| SD | 9.84 | 11.29 | 15.64 | 14.60 |
| Minimum | 74 | -32 | 74 | -89 |
| Q1 | 91.0 | -1.0 | 90.0 | -1.0 |
| Median | 97.0 | 5.0 | 95.5 | 3.0 |
| Q3 | 103.0 | 11.0 | 101.0 | 7.0 |
| Maximum | 136 | 45 | 220 | 86 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 97.0 | 4.0 | 98.0 | 2.9 |
| SD | 9.95 | 9.71 | 15.10 | 16.27 |
| Minimum | 73 | -23 | 78 | -86 |
| Q1 | 91.0 | -1.0 | 91.0 | -2.0 |
| Median | 96.0 | 4.0 | 95.0 | 3.0 |
| Q3 | 101.0 | 8.0 | 101.0 | 8.0 |
| Maximum | 145 | 50 | 189 | 81 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 96.0 | 3.2 | 97.6 | 2.6 |
| SD | 15.21 | 16.10 | 18.27 | 19.01 |
| Minimum | 61 | -26 | 75 | -86 |
| Q1 | 89.0 | -5.0 | 89.0 | -3.0 |
| Median | 95.0 | 1.0 | 94.0 | 3.0 |
| Q3 | 101.0 | 8.0 | 101.0 | 7.0 |
| Maximum | 191 | 105 | 241 | 145 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HGB A1C (%)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 5.30 | | 5.31 | |
| SD | 0.398 | | 0.375 | |
| Minimum | 3.9 | | 4.5 | |
| Q1 | 5.10 | | 5.10 | |
| Median | 5.30 | | 5.30 | |
| Q3 | 5.60 | | 5.60 | |
| Maximum | 6.5 | | 7.2 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 5.41 | 0.11 | 5.39 | 0.07 |
| SD | 0.388 | 0.199 | 0.363 | 0.221 |
| Minimum | 3.6 | -0.5 | 4.6 | -0.9 |
| Q1 | 5.20 | 0.00 | 5.20 | 0.00 |
| Median | 5.40 | 0.10 | 5.40 | 0.10 |
| Q3 | 5.70 | 0.20 | 5.60 | 0.20 |
| Maximum | 6.6 | 0.6 | 7.0 | 0.7 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 5.55 | 0.24 | 5.53 | 0.21 |
| SD | 0.285 | 0.308 | 0.344 | 0.302 |
| Minimum | 4.6 | -0.8 | 4.5 | -0.6 |
| Q1 | 5.40 | 0.00 | 5.30 | 0.00 |
| Median | 5.60 | 0.20 | 5.50 | 0.20 |
| Q3 | 5.70 | 0.40 | 5.70 | 0.40 |
| Maximum | 6.3 | 1.1 | 7.0 | 1.2 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HGB A1C (%)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 5.60 | 0.29 | 5.60 | 0.28 |
| SD | 0.262 | 0.381 | 0.366 | 0.344 |
| Minimum | 5.0 | -0.6 | 4.6 | -0.6 |
| Q1 | 5.40 | 0.10 | 5.40 | 0.10 |
| Median | 5.60 | 0.20 | 5.60 | 0.20 |
| Q3 | 5.70 | 0.40 | 5.80 | 0.40 |
| Maximum | 6.6 | 1.4 | 7.3 | 1.6 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 5.56 | 0.24 | 5.55 | 0.24 |
| SD | 0.273 | 0.346 | 0.375 | 0.309 |
| Minimum | 4.8 | -0.4 | 4.6 | -0.3 |
| Q1 | 5.40 | 0.00 | 5.40 | 0.00 |
| Median | 5.60 | 0.20 | 5.50 | 0.20 |
| Q3 | 5.70 | 0.40 | 5.70 | 0.40 |
| Maximum | 6.5 | 1.3 | 7.6 | 1.3 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 5.49 | 0.18 | 5.49 | 0.17 |
| SD | 0.347 | 0.232 | 0.396 | 0.272 |
| Minimum | 3.8 | -0.4 | 4.6 | -0.4 |
| Q1 | 5.30 | 0.00 | 5.30 | 0.00 |
| Median | 5.50 | 0.10 | 5.40 | 0.20 |
| Q3 | 5.70 | 0.30 | 5.60 | 0.30 |
| Maximum | 6.5 | 0.9 | 8.0 | 1.4 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HGB A1C (%)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 5.47 | 0.16 | 5.48 | 0.16 |
| SD | 0.319 | 0.244 | 0.431 | 0.286 |
| Minimum | 4.2 | -0.8 | 4.6 | -0.5 |
| Q1 | 5.30 | 0.00 | 5.20 | 0.00 |
| Median | 5.50 | 0.10 | 5.40 | 0.10 |
| Q3 | 5.70 | 0.30 | 5.60 | 0.30 |
| Maximum | 6.5 | 0.9 | 8.3 | 1.6 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 5.44 | 0.14 | 5.51 | 0.20 |
| SD | 0.320 | 0.293 | 0.439 | 0.341 |
| Minimum | 4.5 | -0.8 | 4.6 | -0.5 |
| Q1 | 5.20 | 0.00 | 5.30 | 0.00 |
| Median | 5.40 | 0.10 | 5.50 | 0.20 |
| Q3 | 5.70 | 0.30 | 5.70 | 0.30 |
| Maximum | 6.3 | 1.1 | 8.2 | 2.5 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 0.612 | | 0.591 | |
| SD | 0.0952 | | 0.0840 | |
| Minimum | 0.39 | | 0.34 | |
| Q1 | 0.560 | | 0.530 | |
| Median | 0.600 | | 0.590 | |
| Q3 | 0.680 | | 0.650 | |
| Maximum | 0.87 | | 0.83 | |
| Week 4 | | | | |
| N | 137 | 137 | 142 | 142 |
| Mean | 0.626 | 0.013 | 0.603 | 0.013 |
| SD | 0.0907 | 0.0425 | 0.0801 | 0.0465 |
| Minimum | 0.40 | -0.10 | 0.43 | -0.10 |
| Q1 | 0.560 | -0.010 | 0.550 | -0.020 |
| Median | 0.620 | 0.010 | 0.600 | 0.010 |
| Q3 | 0.680 | 0.050 | 0.660 | 0.040 |
| Maximum | 0.89 | 0.12 | 0.79 | 0.15 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 0.618 | 0.006 | 0.600 | 0.009 |
| SD | 0.0916 | 0.0513 | 0.0780 | 0.0498 |
| Minimum | 0.41 | -0.14 | 0.30 | -0.15 |
| Q1 | 0.560 | -0.030 | 0.550 | -0.030 |
| Median | 0.610 | 0.010 | 0.595 | 0.010 |
| Q3 | 0.680 | 0.040 | 0.650 | 0.040 |
| Maximum | 0.88 | 0.12 | 0.81 | 0.17 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 0.608 | -0.002 | 0.593 | 0.002 |
| SD | 0.0874 | 0.0597 | 0.0785 | 0.0536 |
| Minimum | 0.38 | -0.15 | 0.42 | -0.15 |
| Q1 | 0.550 | -0.040 | 0.540 | -0.030 |
| Median | 0.610 | 0.000 | 0.600 | 0.000 |
| Q3 | 0.670 | 0.040 | 0.650 | 0.040 |
| Maximum | 0.84 | 0.13 | 0.78 | 0.14 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 0.605 | -0.005 | 0.587 | -0.004 |
| SD | 0.0891 | 0.0561 | 0.0806 | 0.0535 |
| Minimum | 0.39 | -0.15 | 0.35 | -0.18 |
| Q1 | 0.550 | -0.040 | 0.540 | -0.040 |
| Median | 0.600 | -0.010 | 0.580 | 0.000 |
| Q3 | 0.670 | 0.030 | 0.650 | 0.030 |
| Maximum | 0.85 | 0.12 | 0.75 | 0.21 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 0.608 | -0.002 | 0.588 | -0.001 |
| SD | 0.0938 | 0.0525 | 0.0819 | 0.0517 |
| Minimum | 0.40 | -0.18 | 0.34 | -0.12 |
| Q1 | 0.550 | -0.040 | 0.540 | -0.040 |
| Median | 0.600 | 0.000 | 0.590 | 0.000 |
| Q3 | 0.670 | 0.040 | 0.640 | 0.030 |
| Maximum | 0.85 | 0.11 | 0.86 | 0.15 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 0.607 | -0.002 | 0.587 | -0.003 |
| SD | 0.0933 | 0.0520 | 0.0788 | 0.0447 |
| Minimum | 0.36 | -0.18 | 0.38 | -0.13 |
| Q1 | 0.540 | -0.040 | 0.530 | -0.040 |
| Median | 0.605 | 0.000 | 0.580 | 0.000 |
| Q3 | 0.680 | 0.030 | 0.650 | 0.030 |
| Maximum | 0.82 | 0.12 | 0.74 | 0.11 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 0.612 | -0.001 | 0.585 | -0.006 |
| SD | 0.0908 | 0.0543 | 0.0793 | 0.0450 |
| Minimum | 0.34 | -0.19 | 0.34 | -0.12 |
| Q1 | 0.550 | -0.030 | 0.530 | -0.040 |
| Median | 0.600 | 0.000 | 0.580 | -0.010 |
| Q3 | 0.670 | 0.030 | 0.640 | 0.020 |
| Maximum | 0.89 | 0.14 | 0.76 | 0.12 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood urea nitrogen (BUN) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 11.1 | | 11.2 | |
| SD | 3.00 | | 2.66 | |
| Minimum | 5 | | 4 | |
| Q1 | 9.0 | | 9.0 | |
| Median | 11.0 | | 11.0 | |
| Q3 | 13.0 | | 13.0 | |
| Maximum | 19 | | 22 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 12.1 | 1.0 | 12.4 | 1.2 |
| SD | 3.16 | 2.29 | 2.78 | 2.62 |
| Minimum | 6 | -6 | 7 | -5 |
| Q1 | 10.0 | 0.0 | 10.0 | -1.0 |
| Median | 12.0 | 1.0 | 12.0 | 1.0 |
| Q3 | 13.0 | 3.0 | 14.0 | 3.0 |
| Maximum | 24 | 7 | 22 | 11 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 12.4 | 1.3 | 12.2 | 1.0 |
| SD | 3.38 | 2.64 | 2.95 | 2.74 |
| Minimum | 5 | -5 | 6 | -5 |
| Q1 | 10.0 | 0.0 | 10.0 | -1.0 |
| Median | 12.0 | 1.0 | 12.0 | 1.0 |
| Q3 | 14.0 | 3.0 | 14.0 | 3.0 |
| Maximum | 23 | 9 | 23 | 12 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood urea nitrogen (BUN) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 12.1 | 1.1 | 11.9 | 0.7 |
| SD | 3.30 | 2.66 | 2.78 | 2.80 |
| Minimum | 4 | -4 | 5 | -8 |
| Q1 | 10.0 | -1.0 | 10.0 | -1.0 |
| Median | 12.0 | 1.0 | 12.0 | 1.0 |
| Q3 | 14.0 | 3.0 | 13.0 | 2.0 |
| Maximum | 24 | 8 | 19 | 9 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 12.3 | 1.3 | 12.0 | 0.8 |
| SD | 3.26 | 2.95 | 2.90 | 2.80 |
| Minimum | 7 | -7 | 5 | -8 |
| Q1 | 10.0 | -1.0 | 10.0 | -1.0 |
| Median | 12.0 | 1.0 | 12.0 | 1.0 |
| Q3 | 14.0 | 3.0 | 14.0 | 2.5 |
| Maximum | 24 | 12 | 24 | 9 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 12.0 | 1.1 | 12.2 | 0.9 |
| SD | 2.88 | 2.85 | 2.90 | 3.10 |
| Minimum | 5 | -9 | 5 | -7 |
| Q1 | 10.0 | -1.0 | 10.0 | -1.0 |
| Median | 12.0 | 1.0 | 12.0 | 1.0 |
| Q3 | 14.0 | 3.0 | 14.0 | 3.0 |
| Maximum | 21 | 10 | 22 | 12 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood urea nitrogen (BUN) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 12.3 | 1.3 | 12.1 | 0.9 |
| SD | 3.15 | 2.58 | 2.61 | 2.54 |
| Minimum | 6 | -6 | 6 | -7 |
| Q1 | 10.0 | 0.0 | 10.0 | -1.0 |
| Median | 12.0 | 1.0 | 12.0 | 1.0 |
| Q3 | 14.0 | 3.0 | 14.0 | 2.0 |
| Maximum | 21 | 10 | 20 | 8 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 11.4 | 0.3 | 12.5 | 1.3 |
| SD | 3.21 | 2.65 | 2.98 | 2.92 |
| Minimum | 4 | -10 | 5 | -7 |
| Q1 | 9.0 | -1.0 | 11.0 | -1.0 |
| Median | 11.0 | 0.0 | 12.0 | 1.0 |
| Q3 | 13.0 | 2.0 | 14.0 | 3.0 |
| Maximum | 23 | 6 | 21 | 7 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatine kinase (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 79.0 | | 75.9 | |
| SD | 39.14 | | 30.58 | |
| Minimum | 27 | | 29 | |
| Q1 | 55.0 | | 56.0 | |
| Median | 70.5 | | 68.0 | |
| Q3 | 94.0 | | 91.0 | |
| Maximum | 278 | | 202 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 85.0 | 6.0 | 83.3 | 7.4 |
| SD | 48.44 | 40.43 | 34.98 | 31.02 |
| Minimum | 35 | -204 | 25 | -92 |
| Q1 | 55.0 | -3.0 | 59.0 | -5.0 |
| Median | 76.5 | 6.5 | 79.0 | 5.5 |
| Q3 | 94.0 | 17.0 | 94.0 | 15.0 |
| Maximum | 340 | 235 | 259 | 157 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 83.4 | 4.0 | 81.2 | 5.3 |
| SD | 44.74 | 38.68 | 28.36 | 23.07 |
| Minimum | 33 | -212 | 35 | -119 |
| Q1 | 56.0 | -8.0 | 63.0 | -3.0 |
| Median | 74.0 | 6.0 | 78.0 | 4.0 |
| Q3 | 98.0 | 17.0 | 93.0 | 16.0 |
| Maximum | 389 | 192 | 187 | 87 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatine kinase (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 84.1 | 5.1 | 88.6 | 12.9 |
| SD | 40.85 | 40.77 | 54.76 | 53.30 |
| Minimum | 34 | -218 | 33 | -115 |
| Q1 | 58.0 | -9.0 | 60.0 | -3.0 |
| Median | 76.5 | 4.0 | 78.0 | 8.0 |
| Q3 | 96.0 | 16.0 | 98.0 | 19.0 |
| Maximum | 320 | 243 | 493 | 402 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 82.0 | 2.7 | 79.7 | 3.5 |
| SD | 39.85 | 35.41 | 28.90 | 24.02 |
| Minimum | 34 | -208 | 32 | -118 |
| Q1 | 62.0 | -7.0 | 59.5 | -7.0 |
| Median | 73.0 | 4.0 | 74.0 | 4.0 |
| Q3 | 97.0 | 16.0 | 94.5 | 15.0 |
| Maximum | 400 | 144 | 195 | 86 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 82.5 | 3.2 | 85.7 | 9.3 |
| SD | 35.41 | 36.11 | 40.85 | 39.18 |
| Minimum | 37 | -221 | 32 | -116 |
| Q1 | 59.0 | -6.0 | 63.0 | -4.0 |
| Median | 75.5 | 5.0 | 77.5 | 7.5 |
| Q3 | 97.0 | 18.0 | 101.5 | 20.5 |
| Maximum | 257 | 120 | 370 | 311 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatine kinase (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 94.2 | 14.6 | 92.1 | 15.6 |
| SD | 117.66 | 108.10 | 65.97 | 62.05 |
| Minimum | 30 | -202 | 31 | -105 |
| Q1 | 61.0 | -4.0 | 66.0 | -3.0 |
| Median | 77.0 | 7.0 | 77.0 | 8.0 |
| Q3 | 105.0 | 20.0 | 95.0 | 20.0 |
| Maximum | 1328 | 1155 | 600 | 508 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 78.0 | -1.2 | 82.0 | 5.9 |
| SD | 36.14 | 36.78 | 35.15 | 32.02 |
| Minimum | 22 | -193 | 30 | -86 |
| Q1 | 55.0 | -14.0 | 63.0 | -5.0 |
| Median | 70.0 | 0.0 | 74.0 | 4.0 |
| Q3 | 93.0 | 14.0 | 94.0 | 13.0 |
| Maximum | 310 | 212 | 266 | 224 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Urate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 4.21 | | 4.24 | |
| SD | 1.025 | | 1.033 | |
| Minimum | 0.4 | | 0.4 | |
| Q1 | 3.70 | | 3.50 | |
| Median | 4.20 | | 4.20 | |
| Q3 | 4.80 | | 4.90 | |
| Maximum | 6.8 | | 7.2 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 4.47 | 0.26 | 4.46 | 0.21 |
| SD | 0.956 | 0.516 | 1.108 | 0.539 |
| Minimum | 0.5 | -1.4 | 0.5 | -1.6 |
| Q1 | 3.90 | -0.10 | 3.80 | -0.10 |
| Median | 4.40 | 0.20 | 4.40 | 0.20 |
| Q3 | 5.10 | 0.60 | 5.20 | 0.50 |
| Maximum | 6.9 | 1.7 | 7.2 | 1.5 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 4.55 | 0.33 | 4.48 | 0.23 |
| SD | 1.097 | 0.600 | 1.045 | 0.568 |
| Minimum | 0.4 | -1.4 | 0.5 | -1.4 |
| Q1 | 3.80 | -0.10 | 3.70 | -0.20 |
| Median | 4.50 | 0.40 | 4.50 | 0.30 |
| Q3 | 5.30 | 0.70 | 5.30 | 0.60 |
| Maximum | 7.3 | 2.0 | 6.7 | 1.5 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Urate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 4.64 | 0.42 | 4.48 | 0.23 |
| SD | 1.108 | 0.595 | 1.062 | 0.559 |
| Minimum | 0.5 | -1.6 | 0.4 | -1.5 |
| Q1 | 4.00 | 0.00 | 3.80 | -0.10 |
| Median | 4.60 | 0.40 | 4.50 | 0.30 |
| Q3 | 5.40 | 0.80 | 5.20 | 0.60 |
| Maximum | 7.3 | 2.3 | 7.0 | 1.5 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 4.63 | 0.40 | 4.46 | 0.21 |
| SD | 1.118 | 0.588 | 1.026 | 0.620 |
| Minimum | 0.5 | -1.1 | 0.4 | -1.9 |
| Q1 | 4.00 | 0.00 | 3.90 | -0.15 |
| Median | 4.60 | 0.40 | 4.50 | 0.25 |
| Q3 | 5.30 | 0.70 | 5.05 | 0.60 |
| Maximum | 8.6 | 2.5 | 7.4 | 1.4 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 4.71 | 0.49 | 4.60 | 0.35 |
| SD | 1.112 | 0.654 | 1.052 | 0.590 |
| Minimum | 0.5 | -0.9 | 0.5 | -1.4 |
| Q1 | 4.10 | 0.00 | 4.00 | 0.00 |
| Median | 4.70 | 0.50 | 4.50 | 0.35 |
| Q3 | 5.30 | 0.90 | 5.15 | 0.75 |
| Maximum | 8.1 | 2.1 | 7.1 | 2.3 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Urate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 4.69 | 0.47 | 4.54 | 0.29 |
| SD | 1.116 | 0.608 | 1.028 | 0.548 |
| Minimum | 0.5 | -1.3 | 0.5 | -1.1 |
| Q1 | 4.00 | 0.00 | 3.90 | -0.10 |
| Median | 4.70 | 0.50 | 4.50 | 0.30 |
| Q3 | 5.30 | 0.80 | 5.30 | 0.60 |
| Maximum | 7.7 | 2.1 | 7.2 | 2.3 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 4.54 | 0.32 | 4.63 | 0.38 |
| SD | 1.101 | 0.568 | 1.036 | 0.574 |
| Minimum | 0.6 | -0.8 | 0.5 | -1.1 |
| Q1 | 4.00 | -0.10 | 4.10 | 0.00 |
| Median | 4.50 | 0.30 | 4.60 | 0.40 |
| Q3 | 5.20 | 0.80 | 5.30 | 0.80 |
| Maximum | 7.8 | 1.9 | 6.9 | 1.9 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 140.3 | | 140.2 | |
| SD | 1.27 | | 1.36 | |
| Minimum | 136 | | 137 | |
| Q1 | 140.0 | | 139.0 | |
| Median | 140.0 | | 140.0 | |
| Q3 | 141.0 | | 141.0 | |
| Maximum | 144 | | 145 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 141.0 | 0.7 | 140.7 | 0.4 |
| SD | 1.52 | 1.63 | 1.47 | 1.55 |
| Minimum | 137 | -6 | 138 | -3 |
| Q1 | 140.0 | 0.0 | 140.0 | -1.0 |
| Median | 141.0 | 1.0 | 141.0 | 1.0 |
| Q3 | 142.0 | 2.0 | 142.0 | 1.0 |
| Maximum | 144 | 5 | 145 | 5 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 141.1 | 0.8 | 141.2 | 1.0 |
| SD | 1.38 | 1.54 | 1.51 | 1.52 |
| Minimum | 137 | -3 | 137 | -3 |
| Q1 | 140.0 | 0.0 | 140.0 | 0.0 |
| Median | 141.0 | 1.0 | 141.0 | 1.0 |
| Q3 | 142.0 | 2.0 | 142.0 | 2.0 |
| Maximum | 145 | 5 | 146 | 5 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 141.2 | 0.8 | 141.4 | 1.2 |
| SD | 1.51 | 1.61 | 1.59 | 1.65 |
| Minimum | 137 | -4 | 137 | -3 |
| Q1 | 140.0 | 0.0 | 141.0 | 0.0 |
| Median | 141.0 | 1.0 | 141.0 | 1.0 |
| Q3 | 142.0 | 2.0 | 142.0 | 2.0 |
| Maximum | 145 | 5 | 148 | 6 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 141.3 | 0.9 | 141.4 | 1.2 |
| SD | 1.24 | 1.57 | 1.34 | 1.39 |
| Minimum | 138 | -3 | 139 | -3 |
| Q1 | 140.0 | 0.0 | 141.0 | 0.0 |
| Median | 141.0 | 1.0 | 141.0 | 1.0 |
| Q3 | 142.0 | 2.0 | 142.0 | 2.0 |
| Maximum | 145 | 6 | 145 | 4 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 141.1 | 0.7 | 141.1 | 0.9 |
| SD | 1.71 | 1.81 | 1.42 | 1.51 |
| Minimum | 135 | -4 | 137 | -3 |
| Q1 | 140.0 | -1.0 | 140.0 | 0.0 |
| Median | 141.0 | 1.0 | 141.0 | 1.0 |
| Q3 | 142.0 | 2.0 | 142.0 | 2.0 |
| Maximum | 146 | 6 | 145 | 4 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 141.2 | 0.8 | 141.3 | 1.0 |
| SD | 1.48 | 1.68 | 1.49 | 1.66 |
| Minimum | 138 | -4 | 138 | -4 |
| Q1 | 140.0 | 0.0 | 140.0 | 0.0 |
| Median | 141.0 | 1.0 | 141.0 | 1.0 |
| Q3 | 142.0 | 2.0 | 142.0 | 2.0 |
| Maximum | 145 | 6 | 146 | 6 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 140.5 | 0.2 | 141.2 | 0.9 |
| SD | 1.71 | 1.88 | 1.65 | 1.79 |
| Minimum | 136 | -5 | 137 | -5 |
| Q1 | 139.0 | -1.0 | 140.0 | 0.0 |
| Median | 140.0 | 0.0 | 141.0 | 1.0 |
| Q3 | 142.0 | 2.0 | 142.0 | 2.0 |
| Maximum | 144 | 4 | 145 | 5 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 4.11 | | 4.09 | |
| SD | 0.260 | | 0.271 | |
| Minimum | 3.4 | | 3.4 | |
| Q1 | 3.90 | | 3.90 | |
| Median | 4.10 | | 4.10 | |
| Q3 | 4.30 | | 4.30 | |
| Maximum | 4.8 | | 5.0 | |
| Week 4 | | | | |
| N | 137 | 137 | 140 | 140 |
| Mean | 4.17 | 0.07 | 4.18 | 0.10 |
| SD | 0.293 | 0.325 | 0.278 | 0.265 |
| Minimum | 3.5 | -1.1 | 3.5 | -0.5 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.10 |
| Median | 4.20 | 0.10 | 4.20 | 0.10 |
| Q3 | 4.30 | 0.30 | 4.40 | 0.20 |
| Maximum | 5.1 | 0.9 | 5.1 | 0.9 |
| Week 8 | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 4.18 | 0.07 | 4.19 | 0.09 |
| SD | 0.242 | 0.298 | 0.291 | 0.296 |
| Minimum | 3.6 | -0.9 | 3.3 | -0.9 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.10 |
| Median | 4.20 | 0.10 | 4.20 | 0.10 |
| Q3 | 4.30 | 0.30 | 4.40 | 0.30 |
| Maximum | 4.9 | 0.9 | 5.1 | 0.8 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 129 | 129 | 139 | 139 |
| Mean | 4.14 | 0.03 | 4.18 | 0.08 |
| SD | 0.288 | 0.305 | 0.289 | 0.284 |
| Minimum | 3.5 | -0.7 | 3.4 | -0.8 |
| Q1 | 3.90 | -0.20 | 4.00 | -0.10 |
| Median | 4.10 | 0.10 | 4.20 | 0.10 |
| Q3 | 4.30 | 0.20 | 4.40 | 0.30 |
| Maximum | 4.9 | 0.7 | 5.0 | 0.9 |
| Week 16 | | | | |
| N | 129 | 129 | 134 | 134 |
| Mean | 4.21 | 0.10 | 4.21 | 0.11 |
| SD | 0.292 | 0.303 | 0.294 | 0.305 |
| Minimum | 3.4 | -1.0 | 3.5 | -0.7 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.10 |
| Median | 4.20 | 0.10 | 4.20 | 0.10 |
| Q3 | 4.40 | 0.20 | 4.40 | 0.30 |
| Maximum | 5.2 | 1.1 | 5.4 | 0.9 |
| Week 20 | | | | |
| N | 124 | 124 | 130 | 130 |
| Mean | 4.20 | 0.09 | 4.22 | 0.12 |
| SD | 0.314 | 0.342 | 0.293 | 0.296 |
| Minimum | 3.6 | -0.8 | 3.5 | -0.6 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.10 |
| Median | 4.20 | 0.10 | 4.20 | 0.10 |
| Q3 | 4.40 | 0.30 | 4.40 | 0.30 |
| Maximum | 5.3 | 1.0 | 4.9 | 1.0 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 129 | 129 |
| Mean | 4.18 | 0.07 | 4.15 | 0.05 |
| SD | 0.274 | 0.318 | 0.281 | 0.315 |
| Minimum | 3.5 | -0.7 | 3.4 | -1.0 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.10 |
| Median | 4.20 | 0.10 | 4.10 | 0.10 |
| Q3 | 4.30 | 0.30 | 4.30 | 0.20 |
| Maximum | 5.1 | 1.0 | 5.0 | 1.1 |
| Follow-up | | | | |
| N | 133 | 133 | 141 | 141 |
| Mean | 4.12 | 0.02 | 4.21 | 0.12 |
| SD | 0.266 | 0.295 | 0.290 | 0.296 |
| Minimum | 3.4 | -0.7 | 3.5 | -0.7 |
| Q1 | 3.90 | -0.20 | 4.00 | 0.00 |
| Median | 4.10 | 0.00 | 4.20 | 0.10 |
| Q3 | 4.30 | 0.20 | 4.40 | 0.30 |
| Maximum | 4.8 | 0.8 | 4.9 | 1.0 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 104.0 | | 104.0 | |
| SD | 1.68 | | 1.61 | |
| Minimum | 100 | | 100 | |
| Q1 | 103.0 | | 103.0 | |
| Median | 104.0 | | 104.0 | |
| Q3 | 105.0 | | 105.0 | |
| Maximum | 108 | | 108 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 103.5 | -0.5 | 103.5 | -0.6 |
| SD | 1.74 | 1.75 | 1.77 | 1.73 |
| Minimum | 99 | -4 | 99 | -7 |
| Q1 | 102.0 | -2.0 | 102.0 | -2.0 |
| Median | 104.0 | 0.0 | 103.0 | -1.0 |
| Q3 | 105.0 | 1.0 | 105.0 | 0.0 |
| Maximum | 109 | 4 | 108 | 5 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 103.1 | -0.9 | 103.3 | -0.7 |
| SD | 1.58 | 1.83 | 1.80 | 1.64 |
| Minimum | 98 | -6 | 99 | -5 |
| Q1 | 102.0 | -2.0 | 102.0 | -2.0 |
| Median | 103.0 | -1.0 | 103.0 | -1.0 |
| Q3 | 104.0 | 0.0 | 104.0 | 0.0 |
| Maximum | 106 | 4 | 108 | 4 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 102.9 | -1.1 | 102.9 | -1.2 |
| SD | 1.70 | 1.82 | 1.86 | 1.98 |
| Minimum | 98 | -6 | 99 | -5 |
| Q1 | 102.0 | -2.0 | 102.0 | -3.0 |
| Median | 103.0 | -1.0 | 103.0 | -1.0 |
| Q3 | 104.0 | 0.0 | 104.0 | 0.0 |
| Maximum | 107 | 4 | 110 | 4 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 103.0 | -1.0 | 103.1 | -0.9 |
| SD | 1.56 | 1.68 | 1.60 | 1.68 |
| Minimum | 99 | -5 | 98 | -5 |
| Q1 | 102.0 | -2.0 | 102.0 | -2.0 |
| Median | 103.0 | -1.0 | 103.0 | -1.0 |
| Q3 | 104.0 | 0.0 | 104.0 | 0.0 |
| Maximum | 107 | 3 | 107 | 4 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 102.8 | -1.2 | 102.8 | -1.3 |
| SD | 1.81 | 1.84 | 1.66 | 1.92 |
| Minimum | 96 | -7 | 98 | -7 |
| Q1 | 102.0 | -2.0 | 102.0 | -2.0 |
| Median | 103.0 | -1.0 | 103.0 | -1.0 |
| Q3 | 104.0 | 0.0 | 104.0 | 0.0 |
| Maximum | 107 | 4 | 108 | 3 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 102.7 | -1.3 | 102.7 | -1.3 |
| SD | 1.60 | 1.76 | 1.65 | 1.73 |
| Minimum | 99 | -5 | 98 | -7 |
| Q1 | 102.0 | -3.0 | 102.0 | -2.0 |
| Median | 103.0 | -1.0 | 103.0 | -1.0 |
| Q3 | 104.0 | 0.0 | 104.0 | 0.0 |
| Maximum | 107 | 3 | 109 | 3 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 103.2 | -0.7 | 102.9 | -1.2 |
| SD | 1.72 | 2.05 | 1.86 | 2.03 |
| Minimum | 97 | -6 | 97 | -6 |
| Q1 | 102.0 | -2.0 | 102.0 | -2.0 |
| Median | 103.0 | -1.0 | 103.0 | -1.0 |
| Q3 | 104.0 | 0.0 | 104.0 | 0.0 |
| Maximum | 107 | 5 | 107 | 4 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 8.83 | | 8.81 | |
| SD | 0.351 | | 0.272 | |
| Minimum | 7.8 | | 8.1 | |
| Q1 | 8.60 | | 8.60 | |
| Median | 8.80 | | 8.80 | |
| Q3 | 9.10 | | 9.00 | |
| Maximum | 9.9 | | 9.6 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 9.11 | 0.28 | 9.07 | 0.25 |
| SD | 0.294 | 0.285 | 0.306 | 0.343 |
| Minimum | 8.4 | -0.5 | 8.4 | -1.0 |
| Q1 | 8.90 | 0.10 | 8.90 | 0.00 |
| Median | 9.10 | 0.30 | 9.10 | 0.30 |
| Q3 | 9.30 | 0.50 | 9.30 | 0.40 |
| Maximum | 10.1 | 1.1 | 10.4 | 1.7 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 9.23 | 0.39 | 9.21 | 0.40 |
| SD | 0.307 | 0.343 | 0.291 | 0.310 |
| Minimum | 8.5 | -0.5 | 8.6 | -0.3 |
| Q1 | 9.00 | 0.20 | 9.00 | 0.20 |
| Median | 9.20 | 0.40 | 9.20 | 0.40 |
| Q3 | 9.40 | 0.60 | 9.40 | 0.60 |
| Maximum | 10.2 | 1.3 | 10.0 | 1.2 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 9.29 | 0.46 | 9.25 | 0.44 |
| SD | 0.355 | 0.357 | 0.296 | 0.304 |
| Minimum | 8.5 | -0.5 | 8.5 | -0.2 |
| Q1 | 9.10 | 0.20 | 9.00 | 0.20 |
| Median | 9.30 | 0.50 | 9.20 | 0.40 |
| Q3 | 9.50 | 0.70 | 9.40 | 0.70 |
| Maximum | 10.4 | 1.3 | 10.0 | 1.2 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 9.28 | 0.44 | 9.26 | 0.45 |
| SD | 0.304 | 0.345 | 0.249 | 0.296 |
| Minimum | 8.5 | -0.5 | 8.7 | -0.6 |
| Q1 | 9.10 | 0.20 | 9.10 | 0.25 |
| Median | 9.30 | 0.40 | 9.20 | 0.50 |
| Q3 | 9.50 | 0.70 | 9.40 | 0.70 |
| Maximum | 10.1 | 1.2 | 9.9 | 1.2 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 9.28 | 0.43 | 9.27 | 0.46 |
| SD | 0.315 | 0.350 | 0.239 | 0.283 |
| Minimum | 8.6 | -0.4 | 8.8 | -0.4 |
| Q1 | 9.10 | 0.20 | 9.10 | 0.30 |
| Median | 9.30 | 0.45 | 9.30 | 0.40 |
| Q3 | 9.40 | 0.70 | 9.40 | 0.70 |
| Maximum | 10.2 | 1.2 | 9.8 | 1.0 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 9.27 | 0.43 | 9.26 | 0.45 |
| SD | 0.348 | 0.363 | 0.279 | 0.317 |
| Minimum | 8.4 | -0.7 | 8.7 | -0.3 |
| Q1 | 9.00 | 0.20 | 9.10 | 0.30 |
| Median | 9.30 | 0.40 | 9.20 | 0.50 |
| Q3 | 9.50 | 0.70 | 9.40 | 0.60 |
| Maximum | 10.6 | 1.3 | 10.0 | 1.2 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 8.99 | 0.16 | 9.19 | 0.38 |
| SD | 0.324 | 0.358 | 0.254 | 0.305 |
| Minimum | 8.2 | -0.8 | 8.6 | -0.6 |
| Q1 | 8.80 | -0.10 | 9.00 | 0.20 |
| Median | 9.00 | 0.20 | 9.20 | 0.40 |
| Q3 | 9.20 | 0.40 | 9.40 | 0.60 |
| Maximum | 10.0 | 1.1 | 9.9 | 1.1 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 3.46 | | 3.34 | |
| SD | 0.420 | | 0.486 | |
| Minimum | 2.3 | | 1.3 | |
| Q1 | 3.10 | | 3.00 | |
| Median | 3.45 | | 3.40 | |
| Q3 | 3.70 | | 3.70 | |
| Maximum | 4.7 | | 4.5 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 3.71 | 0.25 | 3.59 | 0.25 |
| SD | 0.419 | 0.441 | 0.501 | 0.438 |
| Minimum | 2.8 | -1.0 | 2.1 | -1.1 |
| Q1 | 3.40 | 0.00 | 3.30 | 0.00 |
| Median | 3.70 | 0.30 | 3.50 | 0.20 |
| Q3 | 4.00 | 0.50 | 3.90 | 0.50 |
| Maximum | 5.0 | 1.3 | 5.1 | 1.6 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 3.86 | 0.41 | 3.76 | 0.42 |
| SD | 0.480 | 0.490 | 0.431 | 0.392 |
| Minimum | 2.8 | -1.1 | 2.3 | -0.6 |
| Q1 | 3.50 | 0.10 | 3.50 | 0.20 |
| Median | 3.90 | 0.50 | 3.80 | 0.40 |
| Q3 | 4.10 | 0.70 | 4.10 | 0.70 |
| Maximum | 5.1 | 1.7 | 4.7 | 1.8 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 3.96 | 0.52 | 3.91 | 0.57 |
| SD | 0.472 | 0.473 | 0.489 | 0.474 |
| Minimum | 2.7 | -0.9 | 2.7 | -0.9 |
| Q1 | 3.70 | 0.20 | 3.60 | 0.30 |
| Median | 3.95 | 0.50 | 3.90 | 0.60 |
| Q3 | 4.30 | 0.80 | 4.20 | 0.80 |
| Maximum | 5.1 | 1.5 | 5.5 | 2.6 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 4.02 | 0.57 | 3.91 | 0.56 |
| SD | 0.416 | 0.481 | 0.503 | 0.482 |
| Minimum | 2.9 | -0.7 | 2.2 | -0.9 |
| Q1 | 3.70 | 0.20 | 3.60 | 0.20 |
| Median | 4.00 | 0.60 | 3.90 | 0.60 |
| Q3 | 4.30 | 0.90 | 4.25 | 0.80 |
| Maximum | 5.1 | 1.6 | 5.1 | 2.0 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 4.00 | 0.55 | 3.93 | 0.60 |
| SD | 0.439 | 0.521 | 0.501 | 0.510 |
| Minimum | 2.9 | -0.5 | 2.2 | -0.8 |
| Q1 | 3.70 | 0.20 | 3.60 | 0.25 |
| Median | 4.00 | 0.50 | 3.90 | 0.60 |
| Q3 | 4.30 | 0.90 | 4.20 | 0.90 |
| Maximum | 5.5 | 2.0 | 5.3 | 2.1 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 4.03 | 0.58 | 4.05 | 0.72 |
| SD | 0.479 | 0.488 | 0.476 | 0.539 |
| Minimum | 2.7 | -0.6 | 2.9 | -0.5 |
| Q1 | 3.70 | 0.30 | 3.70 | 0.40 |
| Median | 4.00 | 0.60 | 4.00 | 0.70 |
| Q3 | 4.30 | 0.90 | 4.30 | 1.00 |
| Maximum | 5.3 | 1.8 | 6.1 | 3.2 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 3.67 | 0.22 | 3.91 | 0.57 |
| SD | 0.438 | 0.480 | 0.489 | 0.480 |
| Minimum | 2.5 | -1.2 | 2.4 | -1.3 |
| Q1 | 3.40 | -0.20 | 3.60 | 0.30 |
| Median | 3.70 | 0.20 | 3.90 | 0.60 |
| Q3 | 3.90 | 0.50 | 4.20 | 0.90 |
| Maximum | 4.8 | 1.4 | 5.7 | 1.9 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Magnesium (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 2.15 | | 2.13 | |
| SD | 0.129 | | 0.135 | |
| Minimum | 1.8 | | 1.8 | |
| Q1 | 2.10 | | 2.00 | |
| Median | 2.15 | | 2.10 | |
| Q3 | 2.20 | | 2.20 | |
| Maximum | 2.4 | | 2.4 | |
| Week 4 | | | | |
| N | 138 | 138 | 142 | 142 |
| Mean | 2.17 | 0.02 | 2.15 | 0.03 |
| SD | 0.130 | 0.136 | 0.148 | 0.134 |
| Minimum | 1.8 | -0.3 | 1.8 | -0.3 |
| Q1 | 2.10 | -0.10 | 2.10 | -0.10 |
| Median | 2.20 | 0.00 | 2.20 | 0.00 |
| Q3 | 2.20 | 0.10 | 2.30 | 0.10 |
| Maximum | 2.6 | 0.5 | 2.5 | 0.4 |
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 2.14 | 0.00 | 2.16 | 0.03 |
| SD | 0.135 | 0.126 | 0.131 | 0.130 |
| Minimum | 1.9 | -0.3 | 1.9 | -0.3 |
| Q1 | 2.10 | -0.10 | 2.10 | -0.10 |
| Median | 2.10 | 0.00 | 2.20 | 0.00 |
| Q3 | 2.20 | 0.10 | 2.20 | 0.10 |
| Maximum | 2.5 | 0.5 | 2.5 | 0.3 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Magnesium (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 2.14 | 0.00 | 2.13 | 0.01 |
| SD | 0.129 | 0.137 | 0.118 | 0.130 |
| Minimum | 1.9 | -0.3 | 1.9 | -0.3 |
| Q1 | 2.10 | -0.10 | 2.10 | -0.10 |
| Median | 2.10 | 0.00 | 2.10 | 0.00 |
| Q3 | 2.20 | 0.10 | 2.20 | 0.10 |
| Maximum | 2.6 | 0.3 | 2.4 | 0.3 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 2.13 | -0.01 | 2.14 | 0.01 |
| SD | 0.123 | 0.125 | 0.126 | 0.137 |
| Minimum | 1.8 | -0.3 | 1.8 | -0.3 |
| Q1 | 2.10 | -0.10 | 2.10 | -0.10 |
| Median | 2.10 | 0.00 | 2.10 | 0.00 |
| Q3 | 2.20 | 0.10 | 2.20 | 0.10 |
| Maximum | 2.5 | 0.3 | 2.4 | 0.3 |
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 2.12 | -0.02 | 2.13 | 0.01 |
| SD | 0.125 | 0.142 | 0.127 | 0.141 |
| Minimum | 1.8 | -0.4 | 1.8 | -0.4 |
| Q1 | 2.00 | -0.10 | 2.00 | -0.10 |
| Median | 2.10 | 0.00 | 2.10 | 0.00 |
| Q3 | 2.20 | 0.10 | 2.20 | 0.10 |
| Maximum | 2.5 | 0.3 | 2.4 | 0.4 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Magnesium (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 2.12 | -0.03 | 2.12 | -0.01 |
| SD | 0.142 | 0.133 | 0.133 | 0.146 |
| Minimum | 1.8 | -0.3 | 1.8 | -0.4 |
| Q1 | 2.00 | -0.10 | 2.00 | -0.10 |
| Median | 2.10 | 0.00 | 2.10 | 0.00 |
| Q3 | 2.20 | 0.10 | 2.20 | 0.10 |
| Maximum | 2.4 | 0.3 | 2.5 | 0.3 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 2.10 | -0.05 | 2.10 | -0.02 |
| SD | 0.134 | 0.134 | 0.138 | 0.125 |
| Minimum | 1.8 | -0.4 | 1.6 | -0.3 |
| Q1 | 2.00 | -0.10 | 2.00 | -0.10 |
| Median | 2.10 | -0.10 | 2.10 | 0.00 |
| Q3 | 2.20 | 0.10 | 2.20 | 0.10 |
| Maximum | 2.4 | 0.3 | 2.5 | 0.3 |

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bile acid (total bile acid [TBA]) (umol/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 3.28 | | 2.94 | |
| SD | 3.010 | | 2.486 | |
| Minimum | 0.5 | | 0.5 | |
| Q1 | 1.30 | | 1.40 | |
| Median | 2.20 | | 2.20 | |
| Q3 | 4.60 | | 3.90 | |
| Maximum | 22.1 | | 15.2 | |
| Week 2 | | | | |
| N | 137 | 137 | 142 | 142 |
| Mean | 3.50 | 0.21 | 3.33 | 0.40 |
| SD | 3.236 | 3.013 | 2.615 | 2.917 |
| Minimum | 0.5 | -8.1 | 0.5 | -10.6 |
| Q1 | 1.60 | -1.10 | 1.60 | -0.90 |
| Median | 2.50 | -0.10 | 2.65 | 0.30 |
| Q3 | 4.20 | 1.40 | 4.20 | 1.10 |
| Maximum | 22.5 | 14.3 | 14.0 | 11.8 |
| Week 4 | | | | |
| N | 137 | 137 | 142 | 142 |
| Mean | 3.81 | 0.57 | 3.49 | 0.55 |
| SD | 3.647 | 3.366 | 2.710 | 2.612 |
| Minimum | 0.6 | -8.6 | 0.6 | -11.0 |
| Q1 | 1.60 | -0.80 | 1.60 | -0.80 |
| Median | 2.80 | 0.30 | 2.75 | 0.40 |
| Q3 | 4.80 | 1.70 | 4.70 | 1.80 |
| Maximum | 24.6 | 18.8 | 18.4 | 12.2 |

治験総括報告書 Table 15.3.2.1.1.2（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bile acid (total bile acid [TBA]) (umol/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 3.54 | 0.30 | 3.34 | 0.40 |
| SD | 3.499 | 2.797 | 3.159 | 3.205 |
| Minimum | 0.5 | -8.1 | 0.5 | -11.4 |
| Q1 | 1.60 | -0.90 | 1.30 | -1.10 |
| Median | 2.60 | 0.20 | 2.25 | 0.25 |
| Q3 | 4.10 | 1.20 | 4.20 | 1.30 |
| Maximum | 27.9 | 15.1 | 18.6 | 13.3 |
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 3.02 | -0.14 | 3.45 | 0.51 |
| SD | 2.015 | 2.835 | 3.143 | 2.880 |
| Minimum | 0.6 | -16.2 | 0.5 | -10.7 |
| Q1 | 1.50 | -0.80 | 1.50 | -0.80 |
| Median | 2.45 | 0.10 | 2.70 | 0.20 |
| Q3 | 4.20 | 0.80 | 4.30 | 1.80 |
| Maximum | 9.8 | 5.1 | 20.3 | 15.2 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 3.46 | 0.28 | 3.09 | 0.22 |
| SD | 2.713 | 2.738 | 2.530 | 2.563 |
| Minimum | 0.6 | -8.5 | 0.6 | -11.2 |
| Q1 | 1.60 | -0.70 | 1.35 | -0.70 |
| Median | 2.80 | 0.30 | 2.45 | 0.20 |
| Q3 | 4.40 | 1.20 | 4.25 | 1.65 |
| Maximum | 18.9 | 11.0 | 19.7 | 6.2 |

治験総括報告書 Table 15.3.2.1.1.2（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bile acid (total bile acid [TBA]) (umol/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 3.32 | 0.13 | 3.69 | 0.86 |
| SD | 2.462 | 2.764 | 4.538 | 4.151 |
| Minimum | 0.6 | -8.0 | 0.5 | -10.9 |
| Q1 | 1.70 | -1.00 | 1.40 | -0.45 |
| Median | 2.60 | 0.25 | 2.85 | 0.35 |
| Q3 | 4.30 | 1.50 | 4.35 | 1.65 |
| Maximum | 14.1 | 10.4 | 38.9 | 33.8 |
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 3.52 | 0.32 | 3.13 | 0.30 |
| SD | 2.828 | 2.485 | 2.516 | 2.888 |
| Minimum | 0.6 | -7.9 | 0.5 | -9.6 |
| Q1 | 1.40 | -0.60 | 1.40 | -0.80 |
| Median | 2.70 | 0.20 | 2.50 | 0.30 |
| Q3 | 4.40 | 1.60 | 4.20 | 1.50 |
| Maximum | 17.1 | 8.3 | 12.3 | 8.5 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 3.33 | 0.12 | 3.69 | 0.76 |
| SD | 2.640 | 2.810 | 2.884 | 3.060 |
| Minimum | 0.5 | -11.2 | 0.5 | -10.1 |
| Q1 | 1.60 | -1.10 | 1.70 | -0.50 |
| Median | 2.60 | 0.10 | 2.90 | 0.60 |
| Q3 | 4.00 | 1.70 | 4.60 | 2.10 |
| Maximum | 18.7 | 7.8 | 14.9 | 10.8 |

治験総括報告書 Table 15.3.2.1.1.2（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glutamate dehydrogenase (GLDH) (U/L)

| | TAK-385 40mg (N=138) | | Leuprorelin (N=142) | |
|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Baseline | | | | |
| N | 138 | | 142 | |
| Mean | 2.816 | | 2.890 | |
| SD | 1.0115 | | 1.1395 | |
| Minimum | 0.91 | | 0.44 | |
| Q1 | 2.080 | | 2.120 | |
| Median | 2.655 | | 2.760 | |
| Q3 | 3.510 | | 3.470 | |
| Maximum | 5.96 | | 6.84 | |
| Week 2 | | | | |
| N | 137 | 137 | 142 | 142 |
| Mean | 3.247 | 0.435 | 3.018 | 0.128 |
| SD | 1.1821 | 1.1667 | 1.3545 | 1.3956 |
| Minimum | 1.03 | -2.48 | 0.28 | -3.34 |
| Q1 | 2.490 | -0.300 | 2.020 | -0.590 |
| Median | 2.950 | 0.330 | 2.770 | -0.050 |
| Q3 | 3.830 | 1.000 | 3.920 | 0.900 |
| Maximum | 7.43 | 4.88 | 8.05 | 5.70 |
| Week 4 | | | | |
| N | 137 | 137 | 142 | 142 |
| Mean | 3.037 | 0.215 | 3.162 | 0.272 |
| SD | 1.3067 | 1.2602 | 1.3211 | 1.4089 |
| Minimum | 0.56 | -2.83 | 0.90 | -3.60 |
| Q1 | 2.230 | -0.640 | 2.110 | -0.500 |
| Median | 2.870 | 0.220 | 3.105 | 0.335 |
| Q3 | 3.600 | 0.910 | 3.920 | 1.070 |
| Maximum | 9.00 | 4.63 | 7.49 | 4.31 |

治験総括報告書 Table 15.3.2.1.1.2（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glutamate dehydrogenase (GLDH) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 8 | | | | |
| N | 135 | 135 | 142 | 142 |
| Mean | 2.987 | 0.187 | 3.129 | 0.239 |
| SD | 1.2597 | 1.4039 | 1.3501 | 1.5354 |
| Minimum | 1.06 | -3.34 | 0.83 | -3.82 |
| Q1 | 2.020 | -0.940 | 2.170 | -0.660 |
| Median | 2.740 | 0.200 | 3.020 | 0.170 |
| Q3 | 3.570 | 1.120 | 3.930 | 1.110 |
| Maximum | 7.26 | 5.31 | 7.57 | 4.57 |
| Week 12 | | | | |
| N | 130 | 130 | 141 | 141 |
| Mean | 2.906 | 0.105 | 3.016 | 0.122 |
| SD | 1.2248 | 1.3539 | 1.4381 | 1.5771 |
| Minimum | 0.75 | -3.83 | 0.47 | -4.01 |
| Q1 | 1.980 | -0.750 | 2.000 | -0.770 |
| Median | 2.705 | 0.030 | 2.720 | 0.010 |
| Q3 | 3.560 | 1.000 | 3.600 | 1.120 |
| Maximum | 6.65 | 3.55 | 9.76 | 7.01 |
| Week 16 | | | | |
| N | 129 | 129 | 136 | 136 |
| Mean | 2.737 | -0.073 | 2.663 | -0.224 |
| SD | 1.2690 | 1.3550 | 1.2875 | 1.4837 |
| Minimum | 0.98 | -2.79 | 0.65 | -4.11 |
| Q1 | 1.820 | -0.900 | 1.850 | -0.990 |
| Median | 2.680 | -0.170 | 2.440 | -0.345 |
| Q3 | 3.310 | 0.610 | 3.235 | 0.585 |
| Maximum | 8.29 | 3.98 | 9.72 | 6.90 |

治験総括報告書 Table 15.3.2.1.1.2（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-33　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glutamate dehydrogenase (GLDH) (U/L)

| Visit / Statistics | TAK-385 40mg (N=138) Observed Value at Visit | TAK-385 40mg (N=138) Change from Baseline | Leuprorelin (N=142) Observed Value at Visit | Leuprorelin (N=142) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 126 | 126 | 132 | 132 |
| Mean | 2.573 | -0.235 | 2.319 | -0.543 |
| SD | 1.0285 | 1.2120 | 0.9367 | 1.1804 |
| Minimum | 0.66 | -2.94 | 0.52 | -4.95 |
| Q1 | 1.890 | -1.140 | 1.665 | -1.170 |
| Median | 2.335 | -0.225 | 2.140 | -0.480 |
| Q3 | 3.090 | 0.490 | 2.840 | 0.100 |
| Maximum | 5.91 | 3.00 | 5.23 | 3.22 |
| Week 24 | | | | |
| N | 122 | 122 | 131 | 131 |
| Mean | 2.355 | -0.468 | 2.209 | -0.659 |
| SD | 0.9739 | 1.1865 | 0.9350 | 1.2053 |
| Minimum | 0.62 | -3.46 | 0.63 | -5.02 |
| Q1 | 1.710 | -1.340 | 1.610 | -1.310 |
| Median | 2.145 | -0.465 | 1.990 | -0.720 |
| Q3 | 2.710 | 0.070 | 2.690 | -0.030 |
| Maximum | 5.48 | 4.07 | 5.38 | 2.46 |
| Follow-up | | | | |
| N | 135 | 135 | 141 | 141 |
| Mean | 2.306 | -0.502 | 2.360 | -0.531 |
| SD | 0.8880 | 1.0460 | 0.9701 | 1.1629 |
| Minimum | 0.63 | -4.29 | 0.60 | -4.82 |
| Q1 | 1.650 | -1.220 | 1.790 | -1.210 |
| Median | 2.160 | -0.470 | 2.210 | -0.510 |
| Q3 | 2.820 | 0.290 | 2.800 | 0.130 |
| Maximum | 4.81 | 2.33 | 5.95 | 3.69 |

治験総括報告書 Table 15.3.2.1.1.2（5.3.5.1-2）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 14.4 | | 13.8 | |
| SD | 8.12 | | 6.41 | |
| Minimum | 8 | | 7 | |
| Q1 | 10.0 | | 9.5 | |
| Median | 11.0 | | 12.0 | |
| Q3 | 15.0 | | 15.0 | |
| Maximum | 43 | | 36 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 16.8 | 2.4 | 14.9 | 1.2 |
| SD | 10.00 | 6.02 | 6.56 | 3.02 |
| Minimum | 8 | -18 | 7 | -10 |
| Q1 | 11.0 | 0.0 | 11.0 | 0.0 |
| Median | 14.0 | 2.0 | 13.5 | 1.0 |
| Q3 | 18.0 | 4.0 | 18.0 | 2.5 |
| Maximum | 62 | 24 | 37 | 7 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 19.8 | 5.3 | 14.7 | 0.9 |
| SD | 14.14 | 7.03 | 6.56 | 3.39 |
| Minimum | 8 | -3 | 7 | -10 |
| Q1 | 11.0 | 1.5 | 11.0 | -1.0 |
| Median | 15.0 | 4.0 | 13.0 | 1.0 |
| Q3 | 22.0 | 7.5 | 16.0 | 3.0 |
| Maximum | 70 | 32 | 39 | 11 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 20.3 | 5.8 | 16.8 | 3.0 |
| SD | 14.33 | 6.76 | 11.15 | 7.89 |
| Minimum | 11 | -3 | 7 | -5 |
| Q1 | 12.5 | 2.0 | 9.0 | -1.0 |
| Median | 15.5 | 4.0 | 14.0 | 2.0 |
| Q3 | 20.0 | 7.0 | 19.0 | 5.0 |
| Maximum | 74 | 31 | 60 | 41 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 18.7 | 4.3 | 15.1 | 1.4 |
| SD | 16.24 | 10.14 | 6.90 | 4.64 |
| Minimum | 8 | -3 | 7 | -8 |
| Q1 | 12.0 | 0.0 | 10.0 | -1.0 |
| Median | 14.0 | 2.0 | 13.0 | 1.5 |
| Q3 | 19.0 | 4.0 | 19.0 | 3.5 |
| Maximum | 93 | 55 | 35 | 16 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 19.3 | | 19.1 | |
| SD | 5.12 | | 5.33 | |
| Minimum | 13 | | 11 | |
| Q1 | 17.0 | | 15.5 | |
| Median | 18.0 | | 18.0 | |
| Q3 | 20.0 | | 21.0 | |
| Maximum | 39 | | 38 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 21.3 | 1.9 | 19.4 | 0.3 |
| SD | 6.18 | 4.48 | 4.99 | 2.70 |
| Minimum | 14 | -12 | 13 | -8 |
| Q1 | 18.0 | 0.0 | 16.0 | -1.0 |
| Median | 20.0 | 2.0 | 18.0 | 0.5 |
| Q3 | 22.0 | 3.0 | 22.0 | 2.0 |
| Maximum | 48 | 19 | 39 | 5 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 23.3 | 3.8 | 19.2 | 0.0 |
| SD | 9.03 | 5.16 | 5.05 | 2.36 |
| Minimum | 14 | -4 | 12 | -5 |
| Q1 | 18.0 | 1.0 | 17.0 | -1.0 |
| Median | 20.0 | 3.0 | 17.0 | 0.0 |
| Q3 | 25.0 | 5.5 | 22.0 | 2.0 |
| Maximum | 54 | 23 | 39 | 5 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 30 | 30 | 31 | 31 |
| Mean | 23.1 | 3.9 | 19.9 | 0.8 |
| SD | 7.87 | 3.93 | 6.97 | 4.64 |
| Minimum | 16 | -1 | 14 | -6 |
| Q1 | 19.0 | 2.0 | 16.0 | -1.0 |
| Median | 20.0 | 3.5 | 18.0 | 0.0 |
| Q3 | 24.0 | 5.0 | 21.0 | 3.0 |
| Maximum | 48 | 19 | 44 | 20 |
| Follow-up | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 21.6 | 2.2 | 19.1 | 0.0 |
| SD | 9.27 | 6.66 | 5.10 | 3.89 |
| Minimum | 13 | -4 | 12 | -8 |
| Q1 | 17.0 | -0.5 | 16.0 | -3.0 |
| Median | 19.5 | 1.0 | 18.0 | 0.0 |
| Q3 | 22.0 | 3.0 | 22.0 | 2.0 |
| Maximum | 64 | 35 | 34 | 10 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Lactate dehydrogenase (LDH) (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 156.1 | | 162.7 | |
| SD | 20.47 | | 24.74 | |
| Minimum | 87 | | 119 | |
| Q1 | 147.0 | | 143.0 | |
| Median | 155.0 | | 166.0 | |
| Q3 | 169.0 | | 178.5 | |
| Maximum | 196 | | 224 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 163.9 | 7.8 | 158.4 | -4.3 |
| SD | 27.20 | 12.54 | 21.66 | 14.92 |
| Minimum | 81 | -24 | 118 | -31 |
| Q1 | 149.0 | 0.0 | 141.5 | -12.0 |
| Median | 158.0 | 8.0 | 152.5 | -6.0 |
| Q3 | 186.0 | 15.0 | 173.0 | 2.5 |
| Maximum | 218 | 44 | 217 | 43 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 166.6 | 10.4 | 160.5 | -2.2 |
| SD | 25.68 | 14.16 | 24.61 | 14.17 |
| Minimum | 92 | -24 | 120 | -38 |
| Q1 | 152.0 | -0.5 | 147.0 | -10.0 |
| Median | 167.5 | 11.0 | 155.0 | 0.0 |
| Q3 | 188.0 | 19.5 | 176.0 | 7.0 |
| Maximum | 208 | 39 | 235 | 25 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Lactate dehydrogenase (LDH) (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 30 | 30 | 31 | 31 |
| Mean | 165.7 | 9.9 | 157.7 | -5.1 |
| SD | 26.73 | 12.16 | 25.24 | 14.95 |
| Minimum | 88 | -12 | 115 | -35 |
| Q1 | 153.0 | 1.0 | 136.0 | -16.0 |
| Median | 163.0 | 7.5 | 157.0 | -6.0 |
| Q3 | 185.0 | 16.0 | 172.0 | 6.0 |
| Maximum | 215 | 36 | 226 | 25 |
| Follow-up | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 159.6 | 2.6 | 155.6 | -6.9 |
| SD | 23.05 | 15.06 | 25.88 | 13.94 |
| Minimum | 91 | -33 | 124 | -43 |
| Q1 | 145.0 | -6.5 | 134.0 | -18.0 |
| Median | 162.5 | 2.0 | 153.0 | -6.0 |
| Q3 | 174.0 | 8.5 | 172.0 | 2.0 |
| Maximum | 200 | 37 | 240 | 16 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Gamma glutamyl transferase (GGT) (U/L)

| | TAK-385 40mg (N=33) | | Placebo (N=32) | |
|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 18.1 | | 18.9 | |
| SD | 16.16 | | 14.37 | |
| Minimum | 6 | | 7 | |
| Q1 | 10.0 | | 9.5 | |
| Median | 15.0 | | 13.5 | |
| Q3 | 21.0 | | 22.5 | |
| Maximum | 99 | | 68 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 19.8 | 1.7 | 19.1 | 0.2 |
| SD | 16.69 | 3.45 | 13.44 | 3.72 |
| Minimum | 7 | -5 | 6 | -11 |
| Q1 | 12.0 | 0.0 | 9.5 | -2.0 |
| Median | 17.0 | 2.0 | 14.0 | 0.0 |
| Q3 | 21.0 | 3.0 | 25.0 | 3.0 |
| Maximum | 103 | 13 | 57 | 8 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 21.8 | 3.7 | 19.6 | 0.3 |
| SD | 19.06 | 4.70 | 13.90 | 3.47 |
| Minimum | 9 | -7 | 7 | -7 |
| Q1 | 12.0 | 1.0 | 10.0 | -1.0 |
| Median | 17.0 | 3.0 | 13.0 | 0.0 |
| Q3 | 26.0 | 6.0 | 24.0 | 1.0 |
| Maximum | 116 | 17 | 66 | 10 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Gamma glutamyl transferase (GGT) (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 23.7 | 5.5 | 21.1 | 1.7 |
| SD | 26.13 | 10.28 | 16.71 | 7.95 |
| Minimum | 7 | -2 | 6 | -10 |
| Q1 | 12.0 | 1.0 | 11.0 | -2.0 |
| Median | 17.5 | 3.0 | 13.0 | 0.0 |
| Q3 | 25.0 | 7.0 | 27.0 | 4.0 |
| Maximum | 156 | 57 | 68 | 39 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 20.5 | 2.4 | 20.2 | 1.3 |
| SD | 19.59 | 5.58 | 14.05 | 5.75 |
| Minimum | 7 | -6 | 6 | -11 |
| Q1 | 11.0 | 0.0 | 9.5 | -1.0 |
| Median | 16.0 | 1.0 | 16.0 | 0.5 |
| Q3 | 23.0 | 3.0 | 23.5 | 4.0 |
| Maximum | 119 | 20 | 58 | 17 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 4.34 | | 4.32 | |
| SD | 0.253 | | 0.267 | |
| Minimum | 3.9 | | 3.8 | |
| Q1 | 4.20 | | 4.15 | |
| Median | 4.30 | | 4.30 | |
| Q3 | 4.50 | | 4.50 | |
| Maximum | 4.9 | | 4.9 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 4.54 | 0.19 | 4.31 | -0.01 |
| SD | 0.247 | 0.240 | 0.220 | 0.225 |
| Minimum | 4.1 | -0.3 | 3.9 | -0.5 |
| Q1 | 4.30 | 0.10 | 4.10 | -0.10 |
| Median | 4.60 | 0.20 | 4.30 | 0.00 |
| Q3 | 4.70 | 0.30 | 4.50 | 0.10 |
| Maximum | 5.0 | 0.6 | 4.8 | 0.5 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 4.51 | 0.18 | 4.34 | 0.02 |
| SD | 0.228 | 0.195 | 0.214 | 0.238 |
| Minimum | 4.1 | -0.1 | 3.9 | -0.4 |
| Q1 | 4.30 | 0.00 | 4.20 | -0.20 |
| Median | 4.50 | 0.20 | 4.40 | 0.00 |
| Q3 | 4.70 | 0.30 | 4.50 | 0.10 |
| Maximum | 5.0 | 0.7 | 4.7 | 0.5 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 4.51 | 0.18 | 4.33 | 0.01 |
| SD | 0.231 | 0.195 | 0.190 | 0.217 |
| Minimum | 4.2 | -0.1 | 3.9 | -0.4 |
| Q1 | 4.40 | 0.00 | 4.20 | -0.10 |
| Median | 4.50 | 0.20 | 4.40 | 0.00 |
| Q3 | 4.60 | 0.30 | 4.50 | 0.10 |
| Maximum | 5.3 | 0.6 | 4.6 | 0.5 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 4.37 | 0.02 | 4.38 | 0.06 |
| SD | 0.196 | 0.218 | 0.233 | 0.233 |
| Minimum | 4.0 | -0.4 | 3.8 | -0.5 |
| Q1 | 4.20 | -0.10 | 4.25 | -0.10 |
| Median | 4.30 | 0.00 | 4.40 | 0.10 |
| Q3 | 4.50 | 0.10 | 4.50 | 0.20 |
| Maximum | 4.8 | 0.4 | 4.7 | 0.5 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline phosphatase (ALP) (U/L)

| | TAK-385 40mg (N=33) | | Placebo (N=32) | |
|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 178.9 | | 177.8 | |
| SD | 45.76 | | 44.62 | |
| Minimum | 98 | | 102 | |
| Q1 | 151.0 | | 146.0 | |
| Median | 170.0 | | 170.0 | |
| Q3 | 209.0 | | 201.5 | |
| Maximum | 284 | | 304 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 185.5 | 6.6 | 180.4 | 2.6 |
| SD | 51.10 | 19.73 | 41.54 | 20.88 |
| Minimum | 107 | -46 | 99 | -55 |
| Q1 | 150.0 | -5.0 | 154.0 | -9.0 |
| Median | 171.0 | 9.0 | 169.5 | 6.0 |
| Q3 | 218.0 | 18.0 | 206.5 | 16.5 |
| Maximum | 316 | 53 | 293 | 35 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 191.7 | 12.1 | 182.3 | 3.1 |
| SD | 49.71 | 18.63 | 48.87 | 22.84 |
| Minimum | 115 | -25 | 108 | -30 |
| Q1 | 151.5 | -3.0 | 145.0 | -10.0 |
| Median | 180.0 | 14.0 | 173.0 | 0.0 |
| Q3 | 227.0 | 28.0 | 209.0 | 13.0 |
| Maximum | 317 | 48 | 295 | 84 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline phosphatase (ALP) (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 200.7 | 21.2 | 183.2 | 4.0 |
| SD | 58.53 | 27.38 | 52.37 | 22.23 |
| Minimum | 119 | -22 | 104 | -34 |
| Q1 | 160.0 | 4.0 | 139.0 | -10.0 |
| Median | 195.5 | 16.0 | 173.0 | 1.0 |
| Q3 | 226.5 | 33.0 | 204.0 | 12.0 |
| Maximum | 391 | 111 | 333 | 56 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 201.8 | 22.9 | 189.3 | 11.5 |
| SD | 54.17 | 24.18 | 48.67 | 17.42 |
| Minimum | 117 | -25 | 106 | -30 |
| Q1 | 167.0 | 10.0 | 157.0 | -1.5 |
| Median | 185.0 | 19.0 | 179.0 | 11.5 |
| Q3 | 233.0 | 36.0 | 217.0 | 22.5 |
| Maximum | 343 | 97 | 319 | 47 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bilirubin (Total bilirubin) (mg/dL)

| | TAK-385 40mg (N=33) | | Placebo (N=32) | |
|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 0.60 | | 0.58 | |
| SD | 0.256 | | 0.214 | |
| Minimum | 0.2 | | 0.2 | |
| Q1 | 0.40 | | 0.40 | |
| Median | 0.50 | | 0.55 | |
| Q3 | 0.80 | | 0.70 | |
| Maximum | 1.6 | | 1.0 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 0.63 | 0.03 | 0.57 | -0.02 |
| SD | 0.286 | 0.196 | 0.204 | 0.182 |
| Minimum | 0.2 | -0.5 | 0.2 | -0.5 |
| Q1 | 0.50 | -0.10 | 0.40 | -0.10 |
| Median | 0.60 | 0.00 | 0.60 | 0.00 |
| Q3 | 0.70 | 0.10 | 0.65 | 0.10 |
| Maximum | 1.9 | 0.5 | 1.2 | 0.3 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 0.67 | 0.07 | 0.58 | 0.00 |
| SD | 0.309 | 0.149 | 0.194 | 0.182 |
| Minimum | 0.3 | -0.1 | 0.3 | -0.4 |
| Q1 | 0.50 | -0.05 | 0.50 | -0.10 |
| Median | 0.60 | 0.05 | 0.50 | 0.00 |
| Q3 | 0.75 | 0.10 | 0.70 | 0.10 |
| Maximum | 2.0 | 0.5 | 1.1 | 0.6 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Bilirubin (Total bilirubin) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 0.64 | 0.04 | 0.61 | 0.03 |
| SD | 0.314 | 0.181 | 0.218 | 0.189 |
| Minimum | 0.3 | -0.2 | 0.3 | -0.4 |
| Q1 | 0.50 | -0.10 | 0.40 | -0.10 |
| Median | 0.60 | 0.00 | 0.60 | 0.10 |
| Q3 | 0.70 | 0.10 | 0.70 | 0.20 |
| Maximum | 2.1 | 0.5 | 1.1 | 0.4 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 0.65 | 0.06 | 0.54 | -0.04 |
| SD | 0.353 | 0.211 | 0.170 | 0.168 |
| Minimum | 0.2 | -0.5 | 0.2 | -0.4 |
| Q1 | 0.40 | 0.00 | 0.40 | -0.20 |
| Median | 0.60 | 0.00 | 0.50 | 0.00 |
| Q3 | 0.80 | 0.10 | 0.70 | 0.10 |
| Maximum | 2.0 | 0.5 | 0.8 | 0.2 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Protein (Total protein) (g/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 7.00 | | 6.94 | |
| SD | 0.470 | | 0.395 | |
| Minimum | 6.2 | | 6.0 | |
| Q1 | 6.70 | | 6.70 | |
| Median | 7.00 | | 6.90 | |
| Q3 | 7.30 | | 7.10 | |
| Maximum | 8.1 | | 7.9 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 7.32 | 0.32 | 6.97 | 0.03 |
| SD | 0.526 | 0.335 | 0.321 | 0.393 |
| Minimum | 6.3 | -0.3 | 6.5 | -1.0 |
| Q1 | 6.90 | 0.10 | 6.75 | -0.25 |
| Median | 7.30 | 0.30 | 6.90 | 0.10 |
| Q3 | 7.60 | 0.50 | 7.20 | 0.30 |
| Maximum | 8.4 | 1.0 | 7.9 | 0.8 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 7.33 | 0.33 | 7.01 | 0.06 |
| SD | 0.519 | 0.333 | 0.331 | 0.388 |
| Minimum | 6.5 | -0.5 | 6.3 | -1.0 |
| Q1 | 6.95 | 0.10 | 6.80 | -0.10 |
| Median | 7.20 | 0.35 | 7.00 | 0.00 |
| Q3 | 7.70 | 0.55 | 7.20 | 0.30 |
| Maximum | 8.4 | 0.9 | 7.6 | 0.9 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Protein (Total protein) (g/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 7.32 | 0.32 | 6.99 | 0.04 |
| SD | 0.467 | 0.343 | 0.274 | 0.343 |
| Minimum | 6.6 | -0.3 | 6.5 | -0.9 |
| Q1 | 7.05 | 0.05 | 6.80 | -0.20 |
| Median | 7.30 | 0.20 | 7.00 | 0.10 |
| Q3 | 7.65 | 0.50 | 7.30 | 0.20 |
| Maximum | 8.3 | 1.3 | 7.5 | 0.6 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 7.03 | 0.03 | 7.05 | 0.11 |
| SD | 0.353 | 0.336 | 0.356 | 0.320 |
| Minimum | 6.3 | -0.6 | 6.5 | -0.6 |
| Q1 | 6.80 | -0.30 | 6.80 | -0.15 |
| Median | 6.90 | 0.00 | 7.00 | 0.10 |
| Q3 | 7.30 | 0.30 | 7.25 | 0.30 |
| Maximum | 7.8 | 0.6 | 8.0 | 0.7 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Cholesterol (Total cholesterol) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 205.5 | | 194.0 | |
| SD | 45.29 | | 31.13 | |
| Minimum | 146 | | 127 | |
| Q1 | 181.0 | | 171.0 | |
| Median | 199.0 | | 194.0 | |
| Q3 | 215.0 | | 217.5 | |
| Maximum | 406 | | 270 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 225.8 | 20.4 | 192.7 | -1.3 |
| SD | 34.75 | 27.40 | 29.38 | 17.88 |
| Minimum | 160 | -84 | 132 | -30 |
| Q1 | 203.0 | 9.0 | 176.0 | -15.0 |
| Median | 228.0 | 26.0 | 188.0 | -3.0 |
| Q3 | 247.0 | 33.0 | 209.5 | 6.5 |
| Maximum | 322 | 75 | 266 | 48 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 225.8 | 20.5 | 197.2 | 4.0 |
| SD | 44.21 | 19.56 | 31.51 | 13.60 |
| Minimum | 157 | -19 | 139 | -28 |
| Q1 | 197.5 | 7.0 | 171.0 | -2.0 |
| Median | 225.5 | 23.5 | 197.0 | 4.0 |
| Q3 | 245.5 | 38.5 | 212.0 | 12.0 |
| Maximum | 399 | 49 | 265 | 38 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Cholesterol (Total cholesterol) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 226.8 | 21.6 | 198.6 | 5.4 |
| SD | 44.79 | 25.25 | 34.51 | 17.35 |
| Minimum | 168 | -47 | 115 | -37 |
| Q1 | 204.0 | 3.0 | 172.0 | -4.0 |
| Median | 218.5 | 19.0 | 200.0 | 4.0 |
| Q3 | 245.0 | 34.5 | 223.0 | 18.0 |
| Maximum | 401 | 76 | 283 | 42 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 217.8 | 12.3 | 197.4 | 3.4 |
| SD | 46.91 | 19.93 | 33.28 | 14.58 |
| Minimum | 157 | -23 | 137 | -29 |
| Q1 | 199.0 | -4.0 | 175.5 | -7.0 |
| Median | 211.0 | 12.0 | 201.5 | 3.5 |
| Q3 | 229.0 | 20.0 | 215.5 | 12.0 |
| Maximum | 440 | 65 | 284 | 37 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: High density lipoprotein (HDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 60.4 | | 66.6 | |
| SD | 15.06 | | 17.10 | |
| Minimum | 40 | | 36 | |
| Q1 | 48.0 | | 55.5 | |
| Median | 59.0 | | 62.5 | |
| Q3 | 67.0 | | 78.0 | |
| Maximum | 105 | | 110 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 63.9 | 3.5 | 64.5 | -2.1 |
| SD | 16.51 | 9.15 | 18.19 | 8.55 |
| Minimum | 36 | -29 | 30 | -21 |
| Q1 | 52.0 | 0.0 | 52.5 | -7.5 |
| Median | 60.0 | 4.0 | 63.5 | -1.0 |
| Q3 | 74.0 | 8.0 | 76.5 | 3.5 |
| Maximum | 106 | 25 | 108 | 13 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 65.2 | 4.9 | 67.0 | 1.0 |
| SD | 16.42 | 7.14 | 16.43 | 6.67 |
| Minimum | 44 | -12 | 40 | -12 |
| Q1 | 53.0 | 2.0 | 55.0 | -3.0 |
| Median | 61.5 | 4.0 | 68.0 | 1.0 |
| Q3 | 77.0 | 7.5 | 78.0 | 6.0 |
| Maximum | 106 | 30 | 109 | 13 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: High density lipoprotein (HDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 65.8 | 5.5 | 67.3 | 1.3 |
| SD | 16.39 | 8.36 | 16.87 | 7.27 |
| Minimum | 42 | -15 | 36 | -10 |
| Q1 | 52.5 | 0.0 | 54.0 | -4.0 |
| Median | 62.5 | 4.5 | 67.0 | 0.0 |
| Q3 | 75.0 | 11.0 | 78.0 | 6.0 |
| Maximum | 102 | 31 | 107 | 23 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 65.1 | 4.7 | 66.8 | 0.2 |
| SD | 14.89 | 7.59 | 16.33 | 8.50 |
| Minimum | 39 | -10 | 34 | -19 |
| Q1 | 58.0 | -1.0 | 55.0 | -5.5 |
| Median | 63.0 | 5.0 | 68.5 | 1.0 |
| Q3 | 72.0 | 9.0 | 79.5 | 4.5 |
| Maximum | 102 | 20 | 102 | 20 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Low density lipoprotein (LDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 128.0 | | 112.3 | |
| SD | 43.10 | | 33.87 | |
| Minimum | 77 | | 53 | |
| Q1 | 105.0 | | 86.5 | |
| Median | 121.0 | | 110.5 | |
| Q3 | 139.0 | | 133.0 | |
| Maximum | 318 | | 192 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 142.1 | 14.1 | 109.8 | -2.6 |
| SD | 33.71 | 22.46 | 33.16 | 14.54 |
| Minimum | 70 | -68 | 22 | -31 |
| Q1 | 121.0 | 5.0 | 91.5 | -13.5 |
| Median | 142.0 | 18.0 | 110.5 | -2.5 |
| Q3 | 160.0 | 25.0 | 121.5 | 8.0 |
| Maximum | 250 | 59 | 191 | 25 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 140.4 | 12.4 | 115.8 | 4.1 |
| SD | 44.55 | 18.32 | 31.12 | 12.43 |
| Minimum | 67 | -22 | 66 | -24 |
| Q1 | 115.0 | -1.5 | 90.0 | -7.0 |
| Median | 134.5 | 10.5 | 113.0 | 8.0 |
| Q3 | 159.5 | 26.0 | 130.0 | 13.0 |
| Maximum | 315 | 44 | 184 | 26 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Low density lipoprotein (LDL) cholesterol (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 140.4 | 12.4 | 115.8 | 4.1 |
| SD | 43.64 | 22.09 | 35.08 | 13.83 |
| Minimum | 83 | -47 | 60 | -21 |
| Q1 | 113.0 | -1.0 | 87.0 | -6.0 |
| Median | 134.5 | 11.0 | 112.0 | 3.0 |
| Q3 | 155.5 | 23.0 | 139.0 | 17.0 |
| Maximum | 308 | 64 | 204 | 33 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 133.4 | 5.4 | 113.0 | 0.7 |
| SD | 43.42 | 16.13 | 31.57 | 13.70 |
| Minimum | 63 | -23 | 63 | -28 |
| Q1 | 117.0 | -7.0 | 90.5 | -8.0 |
| Median | 127.0 | 8.0 | 111.0 | -1.0 |
| Q3 | 149.0 | 15.0 | 133.0 | 9.5 |
| Maximum | 331 | 55 | 190 | 32 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 99.1 | | 98.7 | |
| SD | 60.28 | | 71.75 | |
| Minimum | 31 | | 23 | |
| Q1 | 62.0 | | 49.5 | |
| Median | 76.0 | | 76.5 | |
| Q3 | 121.0 | | 121.0 | |
| Maximum | 276 | | 332 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 112.5 | 13.4 | 111.3 | 12.7 |
| SD | 72.19 | 40.01 | 160.12 | 156.57 |
| Minimum | 37 | -78 | 35 | -189 |
| Q1 | 64.0 | -14.0 | 47.5 | -22.0 |
| Median | 95.0 | 6.0 | 92.5 | -1.5 |
| Q3 | 143.0 | 40.0 | 103.0 | 16.5 |
| Maximum | 338 | 104 | 967 | 817 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 114.5 | 15.0 | 81.2 | -19.2 |
| SD | 67.80 | 47.78 | 40.39 | 49.39 |
| Minimum | 40 | -106 | 30 | -170 |
| Q1 | 60.0 | -11.0 | 45.0 | -41.0 |
| Median | 95.0 | 14.5 | 69.0 | -9.0 |
| Q3 | 158.0 | 38.0 | 116.0 | 6.0 |
| Maximum | 326 | 135 | 183 | 58 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 121.6 | 22.1 | 86.7 | -13.7 |
| SD | 64.15 | 51.85 | 41.70 | 66.94 |
| Minimum | 38 | -78 | 32 | -244 |
| Q1 | 74.0 | 2.0 | 56.0 | -32.0 |
| Median | 105.0 | 13.0 | 78.0 | 0.0 |
| Q3 | 165.0 | 37.5 | 117.0 | 25.0 |
| Maximum | 310 | 154 | 173 | 94 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 96.8 | -2.3 | 109.7 | 11.1 |
| SD | 40.27 | 39.65 | 106.08 | 87.13 |
| Minimum | 48 | -108 | 35 | -141 |
| Q1 | 60.0 | -24.0 | 53.5 | -15.5 |
| Median | 90.0 | 4.0 | 78.0 | 5.5 |
| Q3 | 121.0 | 23.0 | 127.0 | 20.5 |
| Maximum | 205 | 66 | 525 | 391 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 95.6 | | 93.3 | |
| SD | 15.98 | | 10.66 | |
| Minimum | 81 | | 77 | |
| Q1 | 88.0 | | 88.0 | |
| Median | 93.0 | | 91.0 | |
| Q3 | 98.0 | | 97.0 | |
| Maximum | 170 | | 119 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 97.6 | 2.0 | 92.1 | -1.2 |
| SD | 14.61 | 19.97 | 11.27 | 12.32 |
| Minimum | 71 | -67 | 72 | -46 |
| Q1 | 90.0 | -4.0 | 84.0 | -6.0 |
| Median | 95.0 | 4.0 | 90.5 | 0.0 |
| Q3 | 103.0 | 11.0 | 97.0 | 4.0 |
| Maximum | 140 | 55 | 127 | 29 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 100.8 | 5.0 | 94.6 | 1.1 |
| SD | 18.00 | 12.15 | 10.35 | 11.93 |
| Minimum | 81 | -19 | 73 | -39 |
| Q1 | 93.0 | 0.0 | 87.0 | -6.0 |
| Median | 97.5 | 6.0 | 97.0 | -1.0 |
| Q3 | 103.5 | 11.5 | 101.0 | 9.0 |
| Maximum | 166 | 44 | 113 | 24 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 98.6 | 2.8 | 93.2 | -0.3 |
| SD | 15.73 | 21.60 | 9.56 | 12.06 |
| Minimum | 73 | -84 | 66 | -28 |
| Q1 | 89.0 | -2.0 | 87.0 | -10.0 |
| Median | 97.0 | 3.5 | 94.0 | 0.0 |
| Q3 | 101.0 | 8.0 | 101.0 | 10.0 |
| Maximum | 142 | 51 | 110 | 21 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 94.8 | -0.8 | 98.4 | 5.1 |
| SD | 11.45 | 18.98 | 15.13 | 15.89 |
| Minimum | 67 | -74 | 73 | -45 |
| Q1 | 89.0 | -7.0 | 90.5 | -3.0 |
| Median | 95.0 | 2.0 | 95.5 | 3.0 |
| Q3 | 98.0 | 6.0 | 106.0 | 15.5 |
| Maximum | 133 | 40 | 154 | 40 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HGB A1C (%)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 5.39 | | 5.30 | |
| SD | 0.274 | | 0.391 | |
| Minimum | 4.8 | | 4.4 | |
| Q1 | 5.20 | | 5.10 | |
| Median | 5.40 | | 5.30 | |
| Q3 | 5.60 | | 5.50 | |
| Maximum | 5.9 | | 6.6 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 5.48 | 0.08 | 5.38 | 0.08 |
| SD | 0.257 | 0.165 | 0.376 | 0.188 |
| Minimum | 5.0 | -0.4 | 4.8 | -0.2 |
| Q1 | 5.30 | 0.00 | 5.15 | 0.00 |
| Median | 5.50 | 0.10 | 5.30 | 0.00 |
| Q3 | 5.70 | 0.20 | 5.55 | 0.20 |
| Maximum | 5.9 | 0.5 | 6.8 | 0.7 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 5.53 | 0.14 | 5.42 | 0.11 |
| SD | 0.292 | 0.233 | 0.327 | 0.215 |
| Minimum | 4.9 | -0.6 | 4.9 | -0.2 |
| Q1 | 5.35 | 0.00 | 5.20 | 0.00 |
| Median | 5.50 | 0.10 | 5.40 | 0.00 |
| Q3 | 5.75 | 0.30 | 5.60 | 0.20 |
| Maximum | 6.1 | 0.7 | 6.5 | 0.7 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HGB A1C (%)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 5.58 | 0.19 | 5.33 | 0.02 |
| SD | 0.293 | 0.265 | 0.402 | 0.246 |
| Minimum | 5.0 | -0.4 | 4.3 | -0.6 |
| Q1 | 5.40 | 0.10 | 5.10 | -0.20 |
| Median | 5.55 | 0.20 | 5.30 | 0.00 |
| Q3 | 5.80 | 0.30 | 5.50 | 0.20 |
| Maximum | 6.1 | 1.0 | 6.4 | 0.5 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 5.41 | 0.02 | 5.31 | 0.00 |
| SD | 0.285 | 0.255 | 0.368 | 0.215 |
| Minimum | 4.7 | -0.4 | 4.4 | -0.5 |
| Q1 | 5.30 | -0.20 | 5.10 | -0.10 |
| Median | 5.40 | 0.00 | 5.30 | 0.00 |
| Q3 | 5.60 | 0.20 | 5.50 | 0.10 |
| Maximum | 5.9 | 0.8 | 6.5 | 0.6 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 0.612 | | 0.592 | |
| SD | 0.0876 | | 0.0959 | |
| Minimum | 0.50 | | 0.46 | |
| Q1 | 0.550 | | 0.515 | |
| Median | 0.590 | | 0.560 | |
| Q3 | 0.680 | | 0.625 | |
| Maximum | 0.82 | | 0.80 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 0.637 | 0.025 | 0.589 | -0.002 |
| SD | 0.0944 | 0.0662 | 0.0823 | 0.0508 |
| Minimum | 0.51 | -0.06 | 0.43 | -0.14 |
| Q1 | 0.570 | -0.010 | 0.515 | -0.040 |
| Median | 0.600 | 0.010 | 0.585 | 0.005 |
| Q3 | 0.710 | 0.050 | 0.640 | 0.020 |
| Maximum | 0.83 | 0.33 | 0.76 | 0.09 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 0.614 | 0.005 | 0.597 | 0.011 |
| SD | 0.0946 | 0.0434 | 0.0914 | 0.0566 |
| Minimum | 0.44 | -0.15 | 0.44 | -0.12 |
| Q1 | 0.530 | -0.015 | 0.520 | -0.030 |
| Median | 0.635 | 0.010 | 0.590 | 0.020 |
| Q3 | 0.670 | 0.030 | 0.660 | 0.050 |
| Maximum | 0.82 | 0.07 | 0.80 | 0.12 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 31 | 31 | 31 | 31 |
| Mean | 0.618 | 0.007 | 0.578 | -0.008 |
| SD | 0.1003 | 0.0491 | 0.0887 | 0.0513 |
| Minimum | 0.47 | -0.12 | 0.44 | -0.15 |
| Q1 | 0.540 | -0.020 | 0.500 | -0.040 |
| Median | 0.610 | 0.010 | 0.570 | -0.020 |
| Q3 | 0.690 | 0.050 | 0.640 | 0.030 |
| Maximum | 0.82 | 0.08 | 0.74 | 0.09 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 0.617 | 0.005 | 0.579 | -0.012 |
| SD | 0.0933 | 0.0527 | 0.0911 | 0.0523 |
| Minimum | 0.44 | -0.07 | 0.42 | -0.16 |
| Q1 | 0.550 | -0.030 | 0.515 | -0.040 |
| Median | 0.610 | 0.000 | 0.575 | -0.020 |
| Q3 | 0.660 | 0.040 | 0.650 | 0.020 |
| Maximum | 0.83 | 0.12 | 0.74 | 0.08 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood urea nitrogen (BUN) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 11.6 | | 11.1 | |
| SD | 2.69 | | 3.40 | |
| Minimum | 8 | | 6 | |
| Q1 | 10.0 | | 9.0 | |
| Median | 11.0 | | 11.0 | |
| Q3 | 14.0 | | 12.5 | |
| Maximum | 17 | | 22 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 12.2 | 0.6 | 11.0 | -0.1 |
| SD | 3.05 | 2.42 | 3.52 | 2.27 |
| Minimum | 8 | -6 | 5 | -5 |
| Q1 | 10.0 | -1.0 | 9.0 | -1.0 |
| Median | 12.0 | 1.0 | 10.0 | 0.0 |
| Q3 | 14.0 | 2.0 | 12.0 | 1.0 |
| Maximum | 21 | 5 | 22 | 5 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 12.5 | 1.1 | 11.8 | 0.7 |
| SD | 2.20 | 2.44 | 3.58 | 3.09 |
| Minimum | 9 | -4 | 6 | -5 |
| Q1 | 11.0 | 0.0 | 10.0 | -1.0 |
| Median | 12.5 | 1.0 | 11.0 | 1.0 |
| Q3 | 14.5 | 2.5 | 13.0 | 3.0 |
| Maximum | 16 | 5 | 22 | 9 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood urea nitrogen (BUN) (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 12.6 | 1.2 | 11.6 | 0.5 |
| SD | 3.43 | 2.42 | 2.99 | 3.09 |
| Minimum | 8 | -5 | 5 | -5 |
| Q1 | 9.0 | 0.0 | 9.0 | -2.0 |
| Median | 12.5 | 1.0 | 13.0 | 0.0 |
| Q3 | 16.0 | 3.0 | 13.0 | 3.0 |
| Maximum | 19 | 6 | 17 | 7 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 11.7 | 0.1 | 11.4 | 0.3 |
| SD | 2.70 | 2.70 | 2.87 | 2.80 |
| Minimum | 6 | -6 | 7 | -5 |
| Q1 | 10.0 | -2.0 | 9.0 | -1.0 |
| Median | 11.0 | 0.0 | 11.5 | 0.0 |
| Q3 | 13.0 | 1.0 | 13.0 | 1.5 |
| Maximum | 19 | 8 | 19 | 9 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatine kinase (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 75.5 | | 83.3 | |
| SD | 28.22 | | 37.70 | |
| Minimum | 29 | | 43 | |
| Q1 | 59.0 | | 60.0 | |
| Median | 68.0 | | 67.5 | |
| Q3 | 92.0 | | 89.0 | |
| Maximum | 144 | | 217 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 83.3 | 7.8 | 84.4 | 1.2 |
| SD | 35.43 | 21.71 | 48.82 | 44.83 |
| Minimum | 29 | -22 | 41 | -63 |
| Q1 | 60.0 | -4.0 | 56.0 | -12.0 |
| Median | 73.0 | 3.0 | 71.0 | -2.0 |
| Q3 | 98.0 | 11.0 | 90.0 | 6.5 |
| Maximum | 167 | 79 | 265 | 204 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 81.7 | 5.9 | 80.0 | -3.1 |
| SD | 46.78 | 39.19 | 36.12 | 30.99 |
| Minimum | 34 | -31 | 38 | -63 |
| Q1 | 61.5 | -9.0 | 54.0 | -21.0 |
| Median | 69.5 | -1.5 | 71.0 | -3.0 |
| Q3 | 90.5 | 9.0 | 93.0 | 10.0 |
| Maximum | 303 | 209 | 182 | 91 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatine kinase (U/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 74.4 | -1.4 | 85.8 | 2.7 |
| SD | 23.22 | 18.10 | 69.77 | 59.41 |
| Minimum | 29 | -46 | 43 | -74 |
| Q1 | 59.5 | -11.5 | 54.0 | -8.0 |
| Median | 70.0 | -0.5 | 72.0 | -3.0 |
| Q3 | 89.0 | 10.5 | 91.0 | 4.0 |
| Maximum | 129 | 42 | 438 | 296 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 69.4 | -6.0 | 77.5 | -5.8 |
| SD | 24.00 | 15.37 | 39.60 | 35.58 |
| Minimum | 32 | -35 | 37 | -72 |
| Q1 | 53.0 | -15.0 | 52.0 | -14.0 |
| Median | 64.0 | -6.0 | 67.0 | -8.0 |
| Q3 | 75.0 | 1.0 | 81.0 | 0.0 |
| Maximum | 118 | 30 | 206 | 151 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Urate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 4.35 | | 4.04 | |
| SD | 0.882 | | 0.952 | |
| Minimum | 3.2 | | 2.3 | |
| Q1 | 3.80 | | 3.30 | |
| Median | 4.10 | | 3.95 | |
| Q3 | 4.90 | | 4.80 | |
| Maximum | 6.8 | | 6.4 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 4.58 | 0.23 | 4.15 | 0.10 |
| SD | 0.828 | 0.507 | 0.973 | 0.428 |
| Minimum | 3.3 | -1.1 | 2.4 | -0.9 |
| Q1 | 4.00 | 0.10 | 3.50 | -0.20 |
| Median | 4.50 | 0.20 | 4.00 | 0.10 |
| Q3 | 5.10 | 0.60 | 4.85 | 0.40 |
| Maximum | 6.7 | 1.3 | 6.2 | 1.2 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 4.67 | 0.34 | 4.20 | 0.14 |
| SD | 1.013 | 0.604 | 0.990 | 0.539 |
| Minimum | 2.8 | -0.9 | 2.7 | -0.8 |
| Q1 | 4.00 | 0.00 | 3.30 | -0.20 |
| Median | 4.60 | 0.50 | 4.20 | 0.20 |
| Q3 | 5.15 | 0.60 | 4.80 | 0.40 |
| Maximum | 7.2 | 1.9 | 6.2 | 1.2 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Urate (mg/dL)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 4.72 | 0.39 | 4.12 | 0.06 |
| SD | 0.820 | 0.582 | 1.082 | 0.512 |
| Minimum | 3.3 | -1.2 | 2.5 | -1.0 |
| Q1 | 4.05 | 0.15 | 3.20 | -0.20 |
| Median | 4.60 | 0.30 | 3.90 | 0.10 |
| Q3 | 5.40 | 0.65 | 4.80 | 0.30 |
| Maximum | 6.3 | 1.9 | 6.5 | 1.5 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 4.50 | 0.15 | 4.13 | 0.08 |
| SD | 0.849 | 0.696 | 1.005 | 0.484 |
| Minimum | 2.9 | -1.5 | 2.3 | -0.7 |
| Q1 | 3.90 | -0.20 | 3.60 | -0.30 |
| Median | 4.50 | 0.00 | 3.95 | 0.00 |
| Q3 | 5.00 | 0.60 | 4.65 | 0.35 |
| Maximum | 6.3 | 1.4 | 6.6 | 1.6 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 140.2 | | 140.4 | |
| SD | 1.08 | | 1.50 | |
| Minimum | 138 | | 137 | |
| Q1 | 139.0 | | 140.0 | |
| Median | 140.0 | | 140.0 | |
| Q3 | 141.0 | | 141.0 | |
| Maximum | 143 | | 144 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 141.1 | 0.9 | 139.8 | -0.5 |
| SD | 1.28 | 1.34 | 1.39 | 1.93 |
| Minimum | 139 | -1 | 136 | -5 |
| Q1 | 140.0 | 0.0 | 139.0 | -2.0 |
| Median | 141.0 | 1.0 | 140.0 | 0.0 |
| Q3 | 142.0 | 2.0 | 141.0 | 1.0 |
| Maximum | 145 | 4 | 142 | 3 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 140.9 | 0.7 | 140.0 | -0.3 |
| SD | 1.90 | 2.04 | 1.49 | 1.97 |
| Minimum | 138 | -3 | 137 | -5 |
| Q1 | 140.0 | -1.0 | 139.0 | -1.0 |
| Median | 141.0 | 1.0 | 140.0 | 0.0 |
| Q3 | 141.5 | 2.0 | 141.0 | 1.0 |
| Maximum | 147 | 6 | 143 | 4 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 141.2 | 0.9 | 139.8 | -0.5 |
| SD | 1.71 | 2.00 | 1.22 | 1.39 |
| Minimum | 138 | -3 | 137 | -4 |
| Q1 | 140.0 | -1.0 | 139.0 | -1.0 |
| Median | 141.0 | 1.0 | 140.0 | -1.0 |
| Q3 | 142.0 | 2.0 | 141.0 | 0.0 |
| Maximum | 145 | 5 | 143 | 2 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 139.8 | -0.4 | 139.5 | -0.8 |
| SD | 1.74 | 1.77 | 1.32 | 1.78 |
| Minimum | 135 | -4 | 137 | -6 |
| Q1 | 139.0 | -2.0 | 138.5 | -2.0 |
| Median | 140.0 | 0.0 | 140.0 | -0.5 |
| Q3 | 141.0 | 0.0 | 140.0 | 0.5 |
| Maximum | 143 | 4 | 143 | 2 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 4.09 | | 4.09 | |
| SD | 0.263 | | 0.279 | |
| Minimum | 3.5 | | 3.5 | |
| Q1 | 4.00 | | 3.85 | |
| Median | 4.10 | | 4.10 | |
| Q3 | 4.30 | | 4.25 | |
| Maximum | 4.6 | | 4.8 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 4.18 | 0.08 | 4.16 | 0.07 |
| SD | 0.311 | 0.336 | 0.271 | 0.327 |
| Minimum | 3.6 | -0.7 | 3.6 | -0.7 |
| Q1 | 3.90 | -0.10 | 4.00 | -0.10 |
| Median | 4.30 | 0.10 | 4.10 | 0.10 |
| Q3 | 4.40 | 0.20 | 4.25 | 0.20 |
| Maximum | 4.8 | 0.9 | 4.8 | 1.0 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 4.20 | 0.11 | 4.16 | 0.07 |
| SD | 0.303 | 0.299 | 0.268 | 0.255 |
| Minimum | 3.5 | -0.6 | 3.5 | -0.6 |
| Q1 | 4.00 | 0.00 | 4.00 | 0.00 |
| Median | 4.20 | 0.10 | 4.20 | 0.10 |
| Q3 | 4.40 | 0.30 | 4.30 | 0.20 |
| Maximum | 4.7 | 0.6 | 4.7 | 0.7 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 30 | 30 | 31 | 31 |
| Mean | 4.21 | 0.12 | 4.10 | 0.01 |
| SD | 0.360 | 0.325 | 0.253 | 0.297 |
| Minimum | 3.7 | -0.5 | 3.4 | -0.6 |
| Q1 | 3.90 | -0.10 | 4.00 | -0.20 |
| Median | 4.15 | 0.10 | 4.10 | 0.00 |
| Q3 | 4.50 | 0.40 | 4.20 | 0.20 |
| Maximum | 4.8 | 0.8 | 4.7 | 0.9 |
| Follow-up | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 4.19 | 0.09 | 4.14 | 0.05 |
| SD | 0.286 | 0.265 | 0.224 | 0.278 |
| Minimum | 3.5 | -0.3 | 3.7 | -0.4 |
| Q1 | 4.00 | -0.10 | 4.00 | -0.20 |
| Median | 4.20 | 0.10 | 4.10 | 0.00 |
| Q3 | 4.35 | 0.30 | 4.30 | 0.30 |
| Maximum | 4.9 | 0.6 | 4.7 | 0.7 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Baseline | | | | |
| N | 33 | | 32 | |
| Mean | 103.5 | | 103.6 | |
| SD | 2.27 | | 1.37 | |
| Minimum | 100 | | 100 | |
| Q1 | 102.0 | | 103.0 | |
| Median | 103.0 | | 103.0 | |
| Q3 | 105.0 | | 105.0 | |
| Maximum | 110 | | 106 | |
| Week 4 | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 102.8 | -0.7 | 103.7 | 0.2 |
| SD | 1.67 | 2.10 | 1.65 | 1.69 |
| Minimum | 98 | -6 | 100 | -5 |
| Q1 | 102.0 | -2.0 | 103.0 | -1.0 |
| Median | 103.0 | 0.0 | 104.0 | 0.0 |
| Q3 | 104.0 | 1.0 | 105.0 | 1.0 |
| Maximum | 106 | 2 | 108 | 3 |
| Week 8 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 102.7 | -0.9 | 103.6 | 0.0 |
| SD | 1.69 | 1.91 | 2.05 | 2.04 |
| Minimum | 99 | -5 | 100 | -4 |
| Q1 | 102.0 | -2.5 | 102.0 | -1.0 |
| Median | 102.0 | 0.0 | 103.0 | 0.0 |
| Q3 | 104.0 | 0.0 | 106.0 | 1.0 |
| Maximum | 106 | 3 | 107 | 4 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

| Visit / Statistics | TAK-385 40mg (N=33) Observed Value at Visit | TAK-385 40mg (N=33) Change from Baseline | Placebo (N=32) Observed Value at Visit | Placebo (N=32) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 32 | 32 | 31 | 31 |
| Mean | 102.3 | -1.3 | 103.1 | -0.4 |
| SD | 1.96 | 2.23 | 1.31 | 1.50 |
| Minimum | 98 | -6 | 99 | -4 |
| Q1 | 101.0 | -3.0 | 103.0 | -1.0 |
| Median | 103.0 | -1.0 | 103.0 | 0.0 |
| Q3 | 104.0 | 0.0 | 104.0 | 0.0 |
| Maximum | 106 | 3 | 105 | 2 |
| Follow-up | | | | |
| N | 33 | 33 | 32 | 32 |
| Mean | 103.0 | -0.5 | 102.8 | -0.7 |
| SD | 1.79 | 1.99 | 1.78 | 1.71 |
| Minimum | 99 | -6 | 98 | -5 |
| Q1 | 102.0 | -2.0 | 101.5 | -2.0 |
| Median | 103.0 | 0.0 | 103.0 | -0.5 |
| Q3 | 104.0 | 1.0 | 104.0 | 1.0 |
| Maximum | 106 | 4 | 106 | 2 |

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用