# An Evaluation of the Efficacy and Safety of E2007 in Patients With Painful Diabetic Neuropathy

This study has been completed.

**Sponsor:**
Eisai Inc.

**Collaborator:**
Eisai Limited

**Information provided by (Responsible Party):**
Eisai Inc.

**ClinicalTrials.gov Identifier:**
NCT00505284

First received: July 20, 2007
Last updated: June 26, 2014
Last verified: February 2013
History of Changes



Results First Received: October 23, 2012

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study;<br>Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator);<br>Primary Purpose: Treatment |
| **Condition:** | Diabetic Neuropathy |
| **Interventions:** | Drug: Placebo<br>Drug: E2007 (2 mg)<br>Drug: E2007 (4 mg)<br>Drug: E2007 (6 mg)<br>Drug: E2007 (8 mg) |

## Participant Flow

Hide Participant Flow

**Recruitment Details**

| Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations |
|---|
| No text entered. |

**Pre-Assignment Details**

| Significant events and approaches for the overall study following participant enrollment, but prior to group assignment |
|---|
| No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Participant Flow: Overall Study**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **STARTED** | 73 | 72 | 69 | 68 | 70 |
| **COMPLETED** | 63 | 56 | 57 | 49 | 37 |
| **NOT COMPLETED** | 10 | 16 | 12 | 19 | 33 |
| **Adverse Event** | 3 | 7 | 9 | 14 | 22 |
| **Protocol Violation** | 0 | 1 | 1 | 0 | 0 |
| **Withdrawal by Subject** | 2 | 6 | 1 | 0 | 6 |
| **Lack of Efficacy** | 0 | 1 | 1 | 1 | 1 |
| **Physician Decision** | 0 | 1 | 0 | 0 | 0 |
| **Not specified** | 5 | 0 | 0 | 4 | 4 |

## Baseline Characteristics

Hide Baseline Characteristics

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg | Total |
|---|---|---|---|---|---|---|
| **Overall Participants Analyzed** [Units: Participants] | 71 | 71 | 68 | 67 | 68 | 345 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Age, Customized** [Units: Participants] | | | | | | |
| **<65 years** | **50** | **50** | **40** | **34** | **41** | **215** |
| **>=65 years** | **21** | **21** | **28** | **33** | **27** | **130** |
| **Gender** [1] [Units: Participants] | | | | | | |
| **Female** | **37** | **27** | **28** | **34** | **25** | **151** |
| **Male** | **34** | **44** | **40** | **33** | **43** | **194** |

[1] Baseline characteristics look at Safety Population (subjects who were randomized, took at least 1 dose of study drug, and had at least 1 post-baseline assessment).

| | | | | | | |
|---|---|---|---|---|---|---|
| **Race/Ethnicity, Customized** [1] [Units: Participants] | | | | | | |
| **White** | **56** | **56** | **56** | **60** | **60** | **288** |
| **Black** | **8** | **11** | **4** | **4** | **6** | **33** |
| **Asian** | **4** | **1** | **2** | **0** | **0** | **7** |
| **Other** | **3** | **3** | **6** | **3** | **2** | **17** |

[1] This baseline characteristic is for Race.

## Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Average Pain Scores From Baseline to Week 15/End of Treatment (EOT) [ Time Frame: Baseline to Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Change in Average Pain Scores From Baseline to Week 15/End of Treatment (EOT) |
| **Measure Description** | Average of last 7 available scores prior to the visit, based on 11-point Likert-type numerical rating scale for pain (0=no pain, to 10=worst possible pain). This is based on a modified baseline observation carried forward (BOCF). |
| **Time Frame** | Baseline to Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Intent-to-Treat (ITT) Population - Randomized subjects who took at least 1 dose of study drug and had at least 1 efficacy assessment at Baseline. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |

| | |
|---|---|
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **Participants Analyzed**<br>[Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Change in Average Pain Scores From Baseline to Week 15/End of Treatment (EOT)**<br>[Units: Scores on a Scale]<br>Mean (Standard Deviation) | **-2.22 (2.19)** | **-1.73 (2.34)** | **-1.30 (2.18)** | **-1.85 (2.01)** | **-1.18 (2.00)** |

**No statistical analysis provided for Change in Average Pain Scores From Baseline to Week 15/End of Treatment (EOT)**

2. Primary: Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 30% Reduction in Pain Score [ Time Frame: Baseline to Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 30% Reduction in Pain Score |
| **Measure Description** | Average pain scores were calculated as the average of last 7 available scores prior to the visit, based on 11-point Likert-type numerical rating scale for pain (0=no pain, to 10=worst possible pain). This is based on a modified BOCF. |
| **Time Frame** | Baseline to Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population. A responder was defined as a subject who had at least a 30% reduction in average pain scores from Baseline to Week 15/EOT. |

**Reporting Groups**

| | Description |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **Participants Analyzed**<br>[Units: Participants] | **73** | **72** | **69** | **68** | **70** |

| | | | | | |
|---|---|---|---|---|---|
| **Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 30% Reduction in Pain Score** [Units: Percentage of Participants] | | | | | |
| **Responders (Yes)** | **56.3** | **36.6** | **32.4** | **39.4** | **31.9** |
| **Non-responders (No)** | **43.7** | **63.4** | **67.6** | **60.6** | **68.1** |

**No statistical analysis provided for Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 30% Reduction in Pain Score**

3. Primary: Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 50% Reduction in Pain Score [ Time Frame: Baseline to Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 50% Reduction in Pain Score |
| **Measure Description** | Average pain scores were calculated as the average of last 7 available scores prior to the visit, based on 11-point Likert-type numerical rating scale for pain (0=no pain, to 10=worst possible pain). This is based on a modified BOCF. |
| **Time Frame** | Baseline to Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population. A responder was defined as a subject who had at least a 50% reduction in average pain scores from Baseline to Week 15/EOT. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | **Placebo** | **Perampanel 2mg** | **Perampanel 4mg** | **Perampanel 6mg** | **Perampanel 8mg** |
|---|---|---|---|---|---|
| **Participants Analyzed** [Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 50% Reduction in Pain Score** [Units: Percentage of Participants] | | | | | |
| **Responders (Yes)** | **38** | **23.9** | **22.1** | **30.3** | **18.8** |
| **Non-responders (No)** | **62** | **76.1** | **77.9** | **69.7** | **81.2** |

**No statistical analysis provided for Responder Rate: Analysis of the Change in Pain Score From Baseline to Week 15/EOT in Subjects Who Had at Least a 50% Reduction in Pain Score**

4. Primary: Mean Change in Average Pain Scores From Baseline at Each Study Week [ Time Frame: Baseline, Week 1 to Week 17 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Mean Change in Average Pain Scores From Baseline at Each Study Week |
| **Measure Description** | Average pain scores were calculated as the average of last 7 available scores prior to the visit, based on 11-point Likert-type numerical rating scale for pain (0=no pain, to 10=worst possible pain). Last on-treatment value refers to last 7 days of available diary data while subject was on double-blind study drug. |
| **Time Frame** | Baseline, Week 1 to Week 17 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | **Placebo** | **Perampanel 2mg** | **Perampanel 4mg** | **Perampanel 6mg** | **Perampanel 8mg** |
|---|---|---|---|---|---|
| **Participants Analyzed**<br>[Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Mean Change in Average Pain Scores From Baseline at Each Study Week**<br>[Units: Scores on a Scale]<br>Mean (Standard Deviation) | | | | | |
| **Week 1** | **-0.58 (1.46)** | **-0.71 (1.33)** | **-0.58 (1.39)** | **-0.79 (1.44)** | **-0.72 (1.33)** |
| **Week 2** | **-0.87 (1.65)** | **-1.09 (1.53)** | **-0.80 (1.55)** | **-1.19 (1.71)** | **-1.05 (1.52)** |
| **Week 3** | **-1.19 (1.85)** | **-1.33 (1.64)** | **-0.91 (1.67)** | **-1.53 (1.92)** | **-1.22 (1.75)** |
| **Week 4** | **-1.46 (1.73)** | **-1.33 (2.01)** | **-1.10 (1.93)** | **-1.75 (1.99)** | **-1.38 (1.97)** |
| **Week 5** | **-1.49 (1.71)** | **-1.55 (2.21)** | **-1.12 (2.08)** | **-1.93 (1.96)** | **-1.56 (1.94)** |
| **Week 6** | **-1.73 (1.81)** | **-1.70 (2.17)** | **-1.31 (2.12)** | **-2.03 (2.14)** | **-1.58 (2.11)** |
| **Week 7** | **-1.99 (1.96)** | **-1.84 (2.10)** | **-1.50 (2.04)** | **-2.31 (2.32)** | **-1.80 (1.98)** |
| **Week 8** | **-1.91 (2.01)** | **-1.86 (2.05)** | **-1.72 (2.20)** | **-2.19 (2.23)** | **-1.71 (2.18)** |

| | | | | | |
|---|---|---|---|---|---|
| **Week 9** | -2.19 (2.10) | -1.86 (2.14) | -1.76 (2.19) | -2.28 (2.12) | -2.01 (2.31) |
| **Week 10** | -2.30 (1.96) | -1.88 (2.19) | -1.84 (2.12) | -2.04 (1.98) | -1.92 (2.08) |
| **Week 11** | -2.39 (2.03) | -1.98 (2.20) | -1.85 (2.14) | -2.10 (2.09) | -1.95 (2.06) |
| **Week 12** | -2.46 (1.99) | -1.81 (2.31) | -1.76 (2.16) | -2.13 (2.11) | -1.91 (2.16) |
| **Week 13** | -2.36 (2.00) | -1.80 (2.16) | -1.62 (2.29) | -2.23 (1.99) | -2.01 (2.17) |
| **Week 14** | -2.30 (2.17) | -1.84 (2.31) | -1.56 (2.27) | -2.25 (2.00) | -1.89 (2.19) |
| **Week 15** | -2.39 (2.23) | -1.99 (2.39) | -1.58 (2.16) | -2.36 (1.91) | -1.93 (2.23) |
| **Week 16** | -2.40 (2.38) | -2.49 (2.20) | -1.50 (2.12) | -1.87 (2.12) | -1.88 (2.01) |
| **Week 17** | NA [1] | -5.50 (3.33) | NA [1] | NA [1] | 0.71 [1] |
| **Last On-Treatment Value** | -2.24 (2.18) | -1.79 (2.32) | -1.48 (2.23) | -2.41 (2.15) | -1.69 (2.24) |

[1] Data unavailable for some arms due to end of study.

**No statistical analysis provided for Mean Change in Average Pain Scores From Baseline at Each Study Week**

5. Secondary: Change in Average Sleep Interference Scores From Baseline to Week 15/EOT [ Time Frame: Baseline to Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change in Average Sleep Interference Scores From Baseline to Week 15/EOT |
| **Measure Description** | Average of last 7 available scores prior to the visit, based on 11-point Likert-type numerical rating scale for sleep interference (0=pain did not interfere with sleep, to 10=pain completely interfered with sleep [unable to sleep]). Based on modified BOCF. |
| **Time Frame** | Baseline to Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | **Placebo** | **Perampanel 2mg** | **Perampanel 4mg** | **Perampanel 6mg** | **Perampanel 8mg** |
|---|---|---|---|---|---|
| **Participants Analyzed** [Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Change in Average Sleep Interference Scores From Baseline to** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Week 15/EOT**<br>[Units: Scores on a Scale]<br>Mean (Standard Deviation) | **-2.17 (2.18)** | **-1.49 (2.11)** | **-1.08 (2.19)** | **-1.71 (2.00)** | **-1.15 (2.19)** |

**No statistical analysis provided for Change in Average Sleep Interference Scores From Baseline to Week 15/EOT**

6. Secondary: Change in Short Form - McGill Pain Questionnaire (SF-MPQ) From Baseline to Week 15/EOT [ Time Frame: Baseline and Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change in Short Form - McGill Pain Questionnaire (SF-MPQ) From Baseline to Week 15/EOT |
| **Measure Description** | SF-MPQ sensory score = sum of intensity scores for descriptors 1-11 (throbbing, shooting, stabbing, sharp, cramping, gnawing, hot-burning, aching, heavy, tender, splitting). Each descriptor scored as 0=none, 1=mild, 2=moderate, or 3=severe. Range of possible sensory scores, 0 to 33, with a score of 33 being the most severe intensity. |
| **Time Frame** | Baseline and Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | **Placebo** | **Perampanel 2mg** | **Perampanel 4mg** | **Perampanel 6mg** | **Perampanel 8mg** |
|---|---|---|---|---|---|
| **Participants Analyzed**<br>[Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Change in Short Form - McGill Pain Questionnaire (SF-MPQ) From Baseline to Week 15/EOT**<br>[Units: Scores on a Scale]<br>Mean (Standard Deviation) | **-5.6 (6.83)** | **-3.9 (6.93)** | **-4.8 (5.83)** | **-6.2 (6.91)** | **-2.9 (5.85)** |

**No statistical analysis provided for Change in Short Form - McGill Pain Questionnaire (SF-MPQ) From Baseline to Week 15/EOT**

7. Secondary: Analysis of Patient Global Impression of Change (PGIC) at Week 15/EOT [ Time Frame: Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Analysis of Patient Global Impression of Change (PGIC) at Week 15/EOT |
| **Measure Description** | At the EOT (Visit 7) or Early Withdrawal Visit (as appropriate), the subject assessed his/her status compared to how they felt before entering the study. This assessment included an evaluation of pain frequency and intensity, the occurrence of AEs, and overall functional status using a 7-point scale where 1=very much improved and 7=very much worse. Using Modified BOCF. |
| **Time Frame** | Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Subset of ITT population used, including subjects that completed PGIC at Week 15 visit, and using BOCF (baseline observation carried forward) subjects that terminated prior to Week 15 received a 'No Change' if due to AE or Lack of Therapeutic Efficacy, subjects who discontinued due to other reasons used PGIC scores from Early Termination visit. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | **Placebo** | **Perampanel 2mg** | **Perampanel 4mg** | **Perampanel 6mg** | **Perampanel 8mg** |
|---|---|---|---|---|---|
| **Participants Analyzed** [Units: Participants] | **66** | **62** | **66** | **62** | **58** |
| **Analysis of Patient Global Impression of Change (PGIC) at Week 15/EOT** [Units: Participants] | | | | | |
| **Very much improved** | **9** | **3** | **4** | **3** | **4** |
| **Much improved** | **17** | **13** | **15** | **14** | **8** |
| **Minimally improved** | **18** | **18** | **20** | **13** | **10** |
| **No change** | **18** | **24** | **24** | **28** | **31** |
| **Minimally worse** | **3** | **3** | **3** | **3** | **4** |
| **Much worse** | **1** | **1** | **0** | **1** | **1** |

**No statistical analysis provided for Analysis of Patient Global Impression of Change (PGIC) at Week 15/EOT**

8. Secondary: Change From Baseline to Week 15/EOT in SF-36 Physical and Mental Component Scores [ Time Frame: Baseline and Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline to Week 15/EOT in SF-36 Physical and Mental Component Scores |
| **Measure Description** | Short Form 36 Health Survey Questionnaire (SF-36) measuring limitations in Physical Components including physical activities, usual role activities (due to physical problems), measuring bodily pain, general health perceptions, and Mental Components including social activities, usual role activities (due to emotional problems), vitality (energy and fatigue. Each of the 8 domains are described by a score ranging from 0 to 100, for a range of total possible scores of 0-400 for physical and 0-400 for mental. Higher scores reflect better subject status. |
| **Time Frame** | Baseline and Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | **Placebo** | **Perampanel 2mg** | **Perampanel 4mg** | **Perampanel 6mg** | **Perampanel 8mg** |
|---|---|---|---|---|---|
| **Participants Analyzed**<br>[Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Change From Baseline to Week 15/EOT in SF-36 Physical and Mental Component Scores**<br>[Units: Scores on a Scale]<br>Mean (Standard Deviation) | | | | | |
| **Physical Component Score** | **4.32 (7.43)** | **1.57 (6.35)** | **1.67 (8.21)** | **1.59 (7.92)** | **0.89 (6.86)** |
| **Mental Component Score** | **-0.26 (9.14)** | **0.40 (8.26)** | **0.06 (10.77)** | **-1.90 (8.74)** | **-1.61 (9.56)** |

**No statistical analysis provided for Change From Baseline to Week 15/EOT in SF-36 Physical and Mental Component Scores**

9. Secondary: Change From Baseline to Week 15/EOT in Hospital Anxiety and Depression Scale (HADS) Anxiety and Depression Subscale Scores [ Time Frame: Baseline and Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline to Week 15/EOT in Hospital Anxiety and Depression Scale (HADS) Anxiety and Depression Subscale Scores |

| | |
|---|---|
| **Measure Description** | HADS anxiety subscale score=sum of scores for 7 anxiety items, each scored on a 4-pt scale (0, 1, 2, or 3), where a higher score indicates worse anxiety. Range of possible HADS anxiety subscale scores, 0 to 21. HADS depression subscale score=sum of scores for 7 depression items, each scored on a 4-pt scale (0, 1, 2, or 3), where a higher score indicates worse depression. Range of possible HADS depression subscale scores, 0 to 21. |
| **Time Frame** | Baseline and Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population |

**Reporting Groups**

| | **Description** |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | **Placebo** | **Perampanel 2mg** | **Perampanel 4mg** | **Perampanel 6mg** | **Perampanel 8mg** |
|---|---|---|---|---|---|
| **Participants Analyzed**<br>[Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Change From Baseline to Week 15/EOT in Hospital Anxiety and Depression Scale (HADS) Anxiety and Depression Subscale Scores**<br>[Units: Scores on a Scale]<br>Mean (Standard Deviation) | | | | | |
| **Anxiety** | **-0.5 (3.01)** | **-0.3 (2.85)** | **-0.5 (3.43)** | **-0.5 (2.89)** | **-0.4 (2.71)** |
| **Depression** | **-0.7 (2.72)** | **-0.4 (2.43)** | **0.0 (3.16)** | **0.1 (3.42)** | **0.2 (2.90)** |

**No statistical analysis provided for Change From Baseline to Week 15/EOT in Hospital Anxiety and Depression Scale (HADS) Anxiety and Depression Subscale Scores**

10. Secondary: Withdrawal Due to Treatment Failure During Double-Blind Dosing Period [ Time Frame: Baseline and Week 15 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Withdrawal Due to Treatment Failure During Double-Blind Dosing Period |
| **Measure Description** | Based on data reported on the End of Study case report form (CRF): If a subject terminated the study early during the Double-blind Dosing Period due to 'lack of therapeutic efficacy,' the subject was counted as a withdrawal due to treatment failure. |
| **Time Frame** | Baseline and Week 15 |
| **Safety Issue** | No |

**Population Description**

| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
|---|
| ITT Population |

**Reporting Groups**

| | Description |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **Participants Analyzed** [Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Withdrawal Due to Treatment Failure During Double-Blind Dosing Period** [Units: Participants] | | | | | |
| **Yes (withdrawn)** | **0** | **1** | **1** | **1** | **1** |
| **No (Not withdrawn)** | **73** | **71** | **68** | **67** | **69** |

**No statistical analysis provided for Withdrawal Due to Treatment Failure During Double-Blind Dosing Period**

11. Secondary: Presence or Absence of Allodynia at Week 15/EOT [ Time Frame: Week 15/EOT ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Presence or Absence of Allodynia at Week 15/EOT |
| **Measure Description** | Investigators rated subjects' allodynia as mild, moderate, severe, or not present. The presence of allodynia (yes/no) at Week 15/EOT was analyzed. |
| **Time Frame** | Week 15/EOT |
| **Safety Issue** | No |

**Population Description**

| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
|---|
| ITT Population |

**Reporting Groups**

| | Description |
|---|---|

| | |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **Participants Analyzed** [Units: Participants] | **73** | **72** | **69** | **68** | **70** |
| **Presence or Absence of Allodynia at Week 15/EOT** [Units: Participants] | | | | | |
| **Yes (Allodynia present)** | **20** | **18** | **19** | **17** | **17** |
| **No (Allodynia absent)** | **47** | **45** | **47** | **48** | **44** |

**No statistical analysis provided for Presence or Absence of Allodynia at Week 15/EOT**

12. Secondary: Analysis of Rescue Analgesic Medication Use (Acetaminophen) During Double-Blind Dosing Period [ Time Frame: Baseline to Week 15 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Analysis of Rescue Analgesic Medication Use (Acetaminophen) During Double-Blind Dosing Period |
| **Measure Description** | If acetaminophen was not reported on the Pain Therapy CRF or on the Concomitant Medication CRF, it was assumed that the subject did not use rescue analgesic medication. |
| **Time Frame** | Baseline to Week 15 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| ITT Population |

**Reporting Groups**

| | Description |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Measured Values**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **Participants Analyzed** [Units: Participants] | 73 | 72 | 69 | 68 | 70 |
| **Analysis of Rescue Analgesic Medication Use (Acetaminophen) During Double-Blind Dosing Period** [Units: Participants] | | | | | |
| **Yes (Used rescue analgesic medication)** | 13 | 9 | 10 | 10 | 13 |
| **No (Did not use rescue analgesic medication)** | 60 | 63 | 59 | 58 | 57 |

**No statistical analysis provided for Analysis of Rescue Analgesic Medication Use (Acetaminophen) During Double-Blind Dosing Period**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | Treatment-emergent adverse events (TEAEs): started on or after (or before if TEAE worsened in severity after first dose) the day of first dose of double-blind study drug up to 30 days after the last dose of double-blind study drug. |
| **Additional Description** | No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Serious Adverse Events**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **Total, serious adverse events** | | | | | |
| **# participants affected / at risk** | 2/71 (2.82%) | 2/71 (2.82%) | 2/68 (2.94%) | 8/67 (11.94%) | 8/68 (11.76%) |
| **Blood and lymphatic system disorders** | | | | | |
| **Anaemia** [1] | | | | | |
| **# participants affected / at risk** | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| **Cardiac disorders** | | | | | |
| **Atrial Fibrillation** [1] | | | | | |
| **# participants affected / at risk** | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 1/68 (1.47%) |
| **Cardiac Failure Congestive** [1] | | | | | |
| **# participants affected / at risk** | 0/71 (0.00%) | 0/71 (0.00%) | 1/68 (1.47%) | 1/67 (1.49%) | 0/68 (0.00%) |

| | | | | | |
|---|---|---|---|---|---|
| Tachycardia [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Ear and labyrinth disorders | | | | | |
| Vertigo [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Gastrointestinal disorders | | | | | |
| Gastrooesophageal Reflux Disease [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 1/71 (1.41%) | 0/68 (0.00%) | 0/67 (0.00%) | 0/68 (0.00%) |
| Pancreatitis Acute [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| General disorders | | | | | |
| Multi-organ Failure [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Death [1] | | | | | |
| # participants affected / at risk | 1/71 (1.41%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 0/68 (0.00%) |
| Hepatobiliary disorders | | | | | |
| Cholelithiasis [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Infections and infestations | | | | | |
| Sepsis [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 1/71 (1.41%) | 0/68 (0.00%) | 2/67 (2.99%) | 0/68 (0.00%) |
| Cellulitis [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Cystitis [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 1/71 (1.41%) | 0/68 (0.00%) | 0/67 (0.00%) | 0/68 (0.00%) |
| Escherichia Infection [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 1/71 (1.41%) | 0/68 (0.00%) | 0/67 (0.00%) | 0/68 (0.00%) |
| Labyrinthitis [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Osteomyelitis [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Pneumonia [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 1/71 (1.41%) | 0/68 (0.00%) | 0/67 (0.00%) | 0/68 (0.00%) |
| Sinusitis [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Urinary Tract Infection [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Wound Infection Staphylococcal [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Injury, poisoning and procedural complications | | | | | |
| Fall [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Investigations | | | | | |
| Blood Pressure Systolic Increased [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |

| | | | | | |
|---|---|---|---|---|---|
| **Metabolism and nutrition disorders** | | | | | |
| Hyperglycaemia [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 1/68 (1.47%) | 0/67 (0.00%) | 0/68 (0.00%) |
| Hypoglycaemia [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | | | | | |
| Basal Cell Carcinoma [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 1/68 (1.47%) | 0/67 (0.00%) | 0/68 (0.00%) |
| Lung Neoplasm Malignant [1] | | | | | |
| # participants affected / at risk | 1/71 (1.41%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 0/68 (0.00%) |
| **Nervous system disorders** | | | | | |
| Aphasia [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Balance Disorder [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Cerebrovascular Accident [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Dizziness [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Encephalopathy [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Syncope [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 1/67 (1.49%) | 0/68 (0.00%) |
| Blood Pressure Fluctuation [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| **Psychiatric disorders** | | | | | |
| Homocidal Ideation [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Suicide Attempt [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| **Renal and urinary disorders** | | | | | |
| Renal Failure Acute [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 1/68 (1.47%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Diabetic Neuropathy [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| Urinary Retention [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| **Reproductive system and breast disorders** | | | | | |
| Benign Prostatic Hyperplasia [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 0/68 (0.00%) | 0/67 (0.00%) | 1/68 (1.47%) |
| **Respiratory, thoracic and mediastinal disorders** | | | | | |
| Asthma [1] | | | | | |
| # participants affected / at risk | 0/71 (0.00%) | 0/71 (0.00%) | 1/68 (1.47%) | 0/67 (0.00%) | 0/68 (0.00%) |
| [1] | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Atelectasis** | | | | | |
| **# participants affected / at risk** | **0/71 (0.00%)** | **0/71 (0.00%)** | **0/68 (0.00%)** | **0/67 (0.00%)** | **1/68 (1.47%)** |
| **Bronchial Hyperreactivity [1]** | | | | | |
| **# participants affected / at risk** | **0/71 (0.00%)** | **0/71 (0.00%)** | **0/68 (0.00%)** | **1/67 (1.49%)** | **0/68 (0.00%)** |

1 Term from vocabulary, MedDRA v. 10.1

## Other Adverse Events

Hide Other Adverse Events

| | |
|---|---|
| **Time Frame** | Treatment-emergent adverse events (TEAEs): started on or after (or before if TEAE worsened in severity after first dose) the day of first dose of double-blind study drug up to 30 days after the last dose of double-blind study drug. |
| **Additional Description** | No text entered. |

**Frequency Threshold**

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 5 |

**Reporting Groups**

| | Description |
|---|---|
| **Placebo** | No text entered. |
| **Perampanel 2mg** | (Perampanel 2mg once daily for 15 weeks) |
| **Perampanel 4mg** | (Perampanel 2mg once daily for 3 weeks, followed by perampanel 4mg once daily for 12 weeks) |
| **Perampanel 6mg** | (Perampanel 2mg once daily for 3 weeks; followed by perampanel 4mg once daily for 3 weeks; and finally, perampanel 6mg once daily for 9 weeks) |
| **Perampanel 8mg** | (Perampanel 2mg once daily for 3 weeks; then, perampanel 4mg once daily for 3 weeks; followed by perampanel 6mg once daily for 3 weeks; and finally, perampanel 8mg once daily for 6 weeks) |

**Other Adverse Events**

| | Placebo | Perampanel 2mg | Perampanel 4mg | Perampanel 6mg | Perampanel 8mg |
|---|---|---|---|---|---|
| **Total, other (not including serious) adverse events** | | | | | |
| **# participants affected / at risk** | **26/71 (36.62%)** | **30/71 (42.25%)** | **33/68 (48.53%)** | **40/67 (59.70%)** | **38/68 (55.88%)** |
| **Gastrointestinal disorders** | | | | | |
| **Diarrhoea [1]** | | | | | |
| **# participants affected / at risk** | **2/71 (2.82%)** | **3/71 (4.23%)** | **1/68 (1.47%)** | **2/67 (2.99%)** | **4/68 (5.88%)** |
| **Nausea [1]** | | | | | |
| **# participants affected / at risk** | **2/71 (2.82%)** | **4/71 (5.63%)** | **2/68 (2.94%)** | **5/67 (7.46%)** | **5/68 (7.35%)** |
| **General disorders** | | | | | |
| **Fatigue [1]** | | | | | |
| **# participants affected / at risk** | **1/71 (1.41%)** | **0/71 (0.00%)** | **3/68 (4.41%)** | **4/67 (5.97%)** | **4/68 (5.88%)** |
| **Gait Disturbance [1]** | | | | | |
| **# participants affected / at risk** | **0/71 (0.00%)** | **2/71 (2.82%)** | **3/68 (4.41%)** | **5/67 (7.46%)** | **3/68 (4.41%)** |
| **Oedema Peripheral [1]** | | | | | |
| **# participants affected / at risk** | **5/71 (7.04%)** | **3/71 (4.23%)** | **5/68 (7.35%)** | **3/67 (4.48%)** | **2/68 (2.94%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Infections and infestations** | | | | | |
| **Nasopharyngitis** [1] | | | | | |
| **# participants affected / at risk** | **3/71 (4.23%)** | **2/71 (2.82%)** | **5/68 (7.35%)** | **1/67 (1.49%)** | **2/68 (2.94%)** |
| **Upper Respiratory Tract Infection** [1] | | | | | |
| **# participants affected / at risk** | **5/71 (7.04%)** | **3/71 (4.23%)** | **2/68 (2.94%)** | **3/67 (4.48%)** | **4/68 (5.88%)** |
| **Injury, poisoning and procedural complications** | | | | | |
| **Contusion** [1] | | | | | |
| **# participants affected / at risk** | **3/71 (4.23%)** | **1/71 (1.41%)** | **3/68 (4.41%)** | **4/67 (5.97%)** | **5/68 (7.35%)** |
| **Fall** [1] | | | | | |
| **# participants affected / at risk** | **2/71 (2.82%)** | **2/71 (2.82%)** | **4/68 (5.88%)** | **7/67 (10.45%)** | **7/68 (10.29%)** |
| **Investigations** | | | | | |
| **Blood Glucose Increased** [1] | | | | | |
| **# participants affected / at risk** | **0/71 (0.00%)** | **4/71 (5.63%)** | **0/68 (0.00%)** | **3/67 (4.48%)** | **0/68 (0.00%)** |
| **Weight Increased** [1] | | | | | |
| **# participants affected / at risk** | **2/71 (2.82%)** | **0/71 (0.00%)** | **2/68 (2.94%)** | **1/67 (1.49%)** | **4/68 (5.88%)** |
| **Musculoskeletal and connective tissue disorders** | | | | | |
| **Back Pain** [1] | | | | | |
| **# participants affected / at risk** | **1/71 (1.41%)** | **4/71 (5.63%)** | **2/68 (2.94%)** | **4/67 (5.97%)** | **2/68 (2.94%)** |
| **Muscle Spasms** [1] | | | | | |
| **# participants affected / at risk** | **1/71 (1.41%)** | **5/71 (7.04%)** | **3/68 (4.41%)** | **4/67 (5.97%)** | **4/68 (5.88%)** |
| **Pain in Extremity** [1] | | | | | |
| **# participants affected / at risk** | **3/71 (4.23%)** | **0/71 (0.00%)** | **2/68 (2.94%)** | **6/67 (8.96%)** | **1/68 (1.47%)** |
| **Nervous system disorders** | | | | | |
| **Dizziness** [1] | | | | | |
| **# participants affected / at risk** | **1/71 (1.41%)** | **6/71 (8.45%)** | **2/68 (2.94%)** | **15/67 (22.39%)** | **15/68 (22.06%)** |
| **Headaches** [1] | | | | | |
| **# participants affected / at risk** | **5/71 (7.04%)** | **2/71 (2.82%)** | **3/68 (4.41%)** | **3/67 (4.48%)** | **4/68 (5.88%)** |
| **Somnolence** [1] | | | | | |
| **# participants affected / at risk** | **2/71 (2.82%)** | **2/71 (2.82%)** | **9/68 (13.24%)** | **5/67 (7.46%)** | **11/68 (16.18%)** |
| **Psychiatric disorders** | | | | | |
| **Insomnia** [1] | | | | | |
| **# participants affected / at risk** | **4/71 (5.63%)** | **1/71 (1.41%)** | **3/68 (4.41%)** | **3/67 (4.48%)** | **1/68 (1.47%)** |
| **Vascular disorders** | | | | | |
| **Hypertension** [1] | | | | | |
| **# participants affected / at risk** | **3/71 (4.23%)** | **1/71 (1.41%)** | **4/68 (5.88%)** | **2/67 (2.99%)** | **1/68 (1.47%)** |
| **Orthostatic Hypotension** [1] | | | | | |
| **# participants affected / at risk** | **0/71 (0.00%)** | **0/71 (0.00%)** | **4/68 (5.88%)** | **0/67 (0.00%)** | **0/68 (0.00%)** |

[1] Term from vocabulary, MedDRA v. 10.1

## Limitations and Caveats

Hide Limitations and Caveats

**Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data**

No text entered.

## More Information

Hide More Information

**Certain Agreements:**

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

**Results Point of Contact:**

Name/Title: Eisai Inc.
Organization: Eisai Call Center
phone: 888-422-4743

| | |
|---|---|
| Responsible Party: | Eisai Inc. |
| ClinicalTrials.gov Identifier: | NCT00505284 History of Changes |
| Other Study ID Numbers: | E2007-G000-227 |
| | 2006-006488-22 ( EudraCT Number ) |
| Study First Received: | July 20, 2007 |
| Results First Received: | October 23, 2012 |
| Last Updated: | June 26, 2014 |
| Health Authority: | United States: Food and Drug Administration |

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK