Trial record 1 of 1 for: 1050235
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# Lurasidone - A 6-week Study of Patients With Bipolar I Depression (Add-on)

This study has been completed.

**Sponsor:**
Sunovion

**Information provided by (Responsible Party):**
Sunovion

**ClinicalTrials.gov Identifier:**
NCT00868452

First received: March 23, 2009
Last updated: March 31, 2014
Last verified: March 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: January 11, 2013

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Intervention Model: Parallel Assignment;<br>Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment |
| **Condition:** | Bipolar Depression |
| **Interventions:** | Drug: lurasidone + (lithium or divalproex)<br>Drug: Placebo + (lithium or divalproex) |

## 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 |
|---|
| 5/11/2009 - 1/9/2012 |

**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 |
|---|---|
| **Lurasidone** | lurasidone + (lithium or divalproex) : lurasidone 20 mg/day for Days 1-2-3, 40 mg/day for Days 4-5-6, and 60 mg/day on Day 7. |
| **Placebo** | Placebo + (lithium or divalproex) : 20 mg/day for Days 1-2-3, 40 mg/day for Days 4-5-6, and 60 mg/day on Day 7 |

**Participant Flow: Overall Study**

| | Lurasidone | Placebo |
|---|---|---|
| STARTED | 183 | 165 |
| COMPLETED | 143 | 136 |
| NOT COMPLETED | 40 | 29 |

## 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.** |
|---|
| Data for full analysis set is provided (intent-to-treat population) |

**Reporting Groups**

| | Description |
|---|---|
| **Lurasidone** | lurasidone + (lithium or divalproex) : lurasidone 20 mg/day for Days 1-2-3, 40 mg/day for Days 4-5-6, and 60 mg/day on Day 7. |
| **Placebo** | Placebo + (lithium or divalproex) : 20 mg/day for Days 1-2-3, 40 mg/day for Days 4-5-6, and 60 mg/day on Day 7 |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | Lurasidone | Placebo | Total |
|---|---|---|---|
| **Number of Participants [units: participants]** | **179** | **161** | **340** |
| **Age [1] [units: participants]** | | | |
| **<=18 years** | **0** | **1** | **1** |
| **Between 18 and 65 years** | **178** | **155** | **333** |
| **>=65 years** | **1** | **5** | **6** |
| **Age [1] [units: years] Mean (Standard Deviation)** | **41.0 (11.53)** | **42.6 (11.75)** | **41.7 (11.65)** |
| **Gender [units: participants]** | | | |
| **Female** | **86** | **76** | **162** |
| **Male** | **93** | **85** | **178** |
| **Region of Enrollment [units: participants]** | | | |
| **France** | **8** | **8** | **16** |
| **United States** | **58** | **52** | **110** |
| **Czech Republic** | **27** | **21** | **48** |
| **Poland** | **9** | **6** | **15** |
| **Ukraine** | **11** | **12** | **23** |
| **Romania** | **2** | **3** | **5** |
| **South Africa** | **10** | **8** | **18** |
| **Russian Federation** | **9** | **10** | **19** |
| **Germany** | **2** | **4** | **6** |
| **India** | **43** | **37** | **80** |

[1] Data for full analysis set is provided.

## Outcome Measures

Show All Outcome Measures

1. Primary: Mean Change From Baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score at Endpoint (Week 6) [ Time Frame: Baseline, Week 6 ]

**Show Outcome Measure 1**

2. Secondary: Mean Change From Baseline to Endpoint (Week 6) in: Clinical Global Impression Bipolar Version, Severity of Illness (CGI-BP-S) Score (Depression) [ Time Frame: Baseline Week 6 ]

**Show Outcome Measure 2**

3. Secondary: Mean Change From Baseline to Endpoint (Week 6) in: Sheehan Disability Scale (SDS) Total Score [ Time Frame: Baselin Week 6 ]

**Show Outcome Measure 3**

## Serious Adverse Events

Show Serious Adverse Events

## Other Adverse Events

Show Other Adverse Events

## 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** 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. |
| The agreement is:<br>☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.<br>☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.<br>Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.<br>☑ **Restriction Description:** In addition to the <60-180 day restriction above, since this is a multicenter study, 1st publication of study results shall be made with other participating study sites as a multicenter publication; provided, if a multicenter publication is not forthcoming within 24 months following completion of study at all sites, the PI shall be free to publish. |

**Results Point of Contact:**

Name/Title: Medical Director, CNS
Organization: Sunovion
phone: 1-866-503-6351

**Publications of Results:**

Loebel A, Cucchiaro J, Silva R, Kroger H, Sarma K, Xu J, Calabrese JR. Lurasidone as adjunctive therapy with lithium or valproate for the treatment of bipolar I depression: a randomized, double-blind, placebo-controlled study. Am J Psychiatry. 2014 Feb;171(2):169-77. doi: 10.1176/appi.ajp.2013.13070985.

**Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):**

Sajatovic M, Forester BP, Tsai J, Kroger H, Pikalov A, Cucchiaro J, Loebel A. Efficacy of Lurasidone in Adults Aged 55 Years and Older With Bipolar Depression: Post Hoc Analysis of 2 Double-Blind, Placebo-Controlled Studies. J Clin Psychiatry. 2016 Aug 16. doi: 10.4088/JCP.15m10261. [Epub ahead of print]

Chapel S, Chiu YY, Hsu J, Cucchiaro J, Loebel A. Lurasidone Dose Response in Bipolar Depression: A Population Dose-response Analysis. Clin Ther. 2016 Jan 1;38(1):4-15. doi: 10.1016/j.clinthera.2015.11.013. Epub 2015 Dec 22.

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|---|---|
| Responsible Party: | Sunovion |
| ClinicalTrials.gov Identifier: | NCT00868452 History of Changes |
| Other Study ID Numbers: | D**1050235**<br>EUDRACT No. 2008-007482-23 |
| Study First Received: | March 23, 2009 |
| Results First Received: | January 11, 2013 |
| Last Updated: | March 31, 2014 |
| Health Authority: | United States: Food and Drug Administration<br>Czech Republic: State Institute for Drug Control<br>France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)<br>India: Drugs Controller General of India<br>Poland: The Central Register of Clinical Trials<br>Russia: Ministry of Health of the Russian Federation<br>South Africa: Medicines Control Council<br>Ukraine: Ministry of Health<br>Romania: National Medicines Agency<br>Germany: Ministry of Health |