Trial record 1 of 1 for: 1050236
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Lurasidone - A 6-week Study of Patients With Bipolar I Depression (Monotherapy)

This study has been completed.

Sponsor:
Sunovion

Information provided by (Responsible Party):
Sunovion

ClinicalTrials.gov Identifier:
NCT00868699

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: February 14, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Bipolar Depression
Interventions:	Drug: lurasidone Drug: Placebo

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
4/29/09 to 2/1/12

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	Placebo : Placebo Comparator
Lurasidone High Arm	lurasidone : lurasidone 20 mg/day for Days 1-2, 40 mg/day for Days 3-4, 60 mg/day for Days 5-6 and 80 mg/day on Day 7 and 80-120 mg/day
Lurasidone Low Arm	lurasidone : lurasidone 20 mg/day for Days 1-7, beginning day 8 flexibly dosed 20-60 mg/day

Participant Flow: Overall Study

	Placebo	Lurasidone High Arm	Lurasidone Low Arm
STARTED	**170**	**169**	**166**

Intent-to-Treat Population	162	162	161
Safety Population	168	167	164
COMPLETED	127	124	123
NOT COMPLETED	43	45	43

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.
Intent-to-treat population is analyzed.

Reporting Groups

	Description
Placebo	Placebo : Placebo Comparator
Lurasidone High Arm	lurasidone : lurasidone 20 mg/day for Days 1-2, 40 mg/day for Days 3-4, 60 mg/day for Days 5-6 and 80 mg/day on Day 7 and 80-120 mg/day
Lurasidone Low Arm	lurasidone : lurasidone 20 mg/day for Days 1-7, beginning day 8 flexibly dosed 20-60 mg/day
Total	Total of all reporting groups

Baseline Measures

	Placebo	Lurasidone High Arm	Lurasidone Low Arm	Total
Number of Participants [units: participants]	**162**	**162**	**161**	**485**
Age [units: participants]				
<=18 years	**0**	**0**	**3**	**3**
Between 18 and 65 years	**159**	**159**	**155**	**473**
>=65 years	**3**	**3**	**3**	**9**
Age [units: years] Mean (Standard Deviation)	**41.2 (12.45)**	**42.0 (12.35)**	**41.3 (12.31)**	**41.5 (12.35)**
Gender [units: participants]				
Female	**87**	**98**	**91**	**276**
Male	**75**	**64**	**70**	**209**
Region of Enrollment [units: participants]				
France	**5**	**4**	**4**	**13**
United States	**58**	**70**	**67**	**195**
Czech Republic	**19**	**19**	**17**	**55**
Ukraine	**16**	**17**	**16**	**49**
Romania	**9**	**2**	**4**	**15**
South Africa	**18**	**17**	**19**	**54**
Russian Federation	**10**	**10**	**11**	**31**

India	27	23	23	73

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 to 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 to 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: Baseline to 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: ☐ 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. ☐ 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. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **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, Hsu J, Sarma K, Sachs G. Lurasidone monotherapy in the treatment of bipolar I depression: a randomized, double-blind, placebo-controlled study. Am J Psychiatry. 2014 Feb;171(2):160-8. doi: 10.1176/appi.ajp.2013.13070984.

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.

Loebel A, Siu C, Rajagopalan K, Pikalov A, Cucchiaro J, Ketter TA. Recovery in bipolar depression: Post-hoc analysis of a placebo-controlled lurasidone trial followed by a long-term continuation study. J Affect Disord. 2015 Nov 1;186:376-82. doi: 10.1016/j.jad.2015.07.033. Epub 2015 Aug 5.

McIntyre RS, Cucchiaro J, Pikalov A, Kroger H, Loebel A. Lurasidone in the treatment of bipolar depression with mixed (subsyndromal hypomanic) features: post hoc analysis of a randomized placebo-controlled trial. J Clin Psychiatry. 2015 Apr;76(4):398-405. doi: 10.4088/JCP.14m09410.

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ClinicalTrials.gov Identifier:	NCT00868699 History of Changes
Other Study ID Numbers:	D**1050236** EUDRACT No. 2008-007457-13
Study First Received:	March 23, 2009
Results First Received:	February 14, 2013
Last Updated:	March 31, 2014
Health Authority:	United States: Food and Drug Administration Czech Republic: State Institute for Drug Control France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) India: Drugs Controller General of India Romania: National Medicines Agency Russia: Ministry of Health of the Russian Federation South Africa: Medicines Control Council Ukraine: Ministry of Health