Trial record 1 of 1 for: 1050231
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Lurasidone HCl A Phase 3 Study of Patients With Acute Schizophrenia

This study has been completed.

Sponsor:
Sunovion

Information provided by (Responsible Party):
Sunovion

ClinicalTrials.gov Identifier:
NCT00615433

First received: February 1, 2008
Last updated: May 19, 2015
Last verified: May 2015
History of Changes

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

Results First Received: November 8, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Schizophrenia
Interventions:	Drug: Lurasidone Drug: Olanzapine Drug: Placebo comparator Drug: Lurasidone 40 mg tablets

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
40mg	Lurasidone 40 mg tablet taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 40 mg treatment group did not take any study medication.
120mg	3 40 mg tablets taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 120 mg treatment group did not take any study medication.

15mg Olz	3 5 mg Olanzapine over-encapsulated capsules taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 15 mg Olanzapine treatment group did not take any study medication.
Placebo	Placebo to match lurasidone 40mg (tablets or placebo to match olanzapine 5 mg (over-encapsulated).

Participant Flow: Overall Study

	40mg	120mg	15mg Olz	Placebo
STARTED	**120**	**119**	**123**	**116**
COMPLETED	**77**	**66**	**84**	**71**
NOT COMPLETED	**43**	**53**	**39**	**45**

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
40mg	Lurasidone 40 mg tablet taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 40 mg treatment group did not take any study medication.
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15mg Olz	3 5 mg Olanzapine over-encapsulated capsules taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 15 mg Olanzapine treatment group did not take any study medication.
Placebo	Placebo to match lurasidone 40mg (tablets or placebo to match olanzapine 5 mg (over-encapsulated).
Total	Total of all reporting groups

Baseline Measures

	40mg	120mg	15mg Olz	Placebo	Total
Overall Participants [units: participants]	**119**	**118**	**122**	**116**	**475**
Age [units: years] Mean (Standard Deviation)	**37.7 (11.0)**	**37.9 (11.2)**	**38.3 (10.2)**	**36.9 (11.3)**	**37.7 (10.9)**
Gender [units: participants]					
Female	**26**	**25**	**27**	**26**	**104**
Male	**93**	**93**	**95**	**90**	**371**
Region of Enrollment [units: participants]					

United States	**70**	**72**	**74**	**68**	**284**
Philippines	**7**	**6**	**8**	**5**	**26**
Lithuania	**7**	**7**	**7**	**8**	**29**
Colombia	**12**	**12**	**12**	**12**	**48**
India	**23**	**21**	**21**	**23**	**88**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Total PANSS (Positive and Negative Syndrome Scale)Score From Baseline to the End of the Double Blind Treatment Period. [Time Frame: Baseline and 6 weeks]

Measure Type	Primary
Measure Title	Change in Total PANSS (Positive and Negative Syndrome Scale)Score From Baseline to the End of the Double Blind Treatment Period.
Measure Description	The PANSS is a 30-item rating instrument evaluating the presence/absence and severity of positive, negative and general psychopathology of schizophrenia. The scale was developed from the BPRS and the Psychopathology Rating Scale. All 30 items are rated on a 7-point scale (1=absent; 7=extreme). The total score can range from 30 to 210. Lower scores represent less severity of illness.
Time Frame	Baseline and 6 weeks
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.
The primary population for the efficacy analysis was the Intent-to-Treat (ITT) population. All subjects who were randomized, received at least one dose of study medication, and have a Baseline efficacy measurement and at least one post-Baseline efficacy measurement, were in the efficacy analysis in the treatment group to which they were randomized.

Reporting Groups

	Description
40mg	Lurasidone 40 mg tablet taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 40 mg treatment group did not take any study medication.
120mg	3 40 mg tablets taken orally once a day.
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Placebo	Placebo to match lurasidone 40mg (tablets or placebo to match olanzapine 5 mg (over-encapsulated).

Measured Values

	40mg	**120mg**	**15mg Olz**	**Placebo**
Overall Participants [units: participants]	**118**	**118**	**121**	**114**
Change in Total PANSS (Positive and Negative Syndrome Scale)Score From Baseline to the End of the Double Blind Treatment Period. [units: Units on a scale] Least Squares Mean (95% Confidence Interval)	**-25.7** **(-29.6 to -21.8)**	**-23.6** **(-27.8 to -19.4)**	**-28.7** **(-32.4 to -24.9)**	**-16.0** **(-20.1 to -12.0)**

Statistical Analysis 1 for Change in Total PANSS (Positive and Negative Syndrome Scale)Score From Baseline to the End of the Double Blind Treatment Period.

Groups [1]	40mg vs. 120mg vs. Placebo
Method [2]	Mixed Models Analysis
P Value [3]	<0.05

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Improvements in PANSS ratings are estimated from 2 prior studies of lurasidone. Assuming lurasidone differs from placebo in change from baseline in PANSS by 6.8 and 10.0 for 40 and 120 mg, respectively, and assuming a standard deviation of 19.1, then n=120 subjects per group provides approximately 97% power (at α=0.05, two-sided) to reject the null hypothesis of no difference from placebo for at least 1 dose. This calculation uses Bonferroni's procedure for controlling pairwise differences.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Secondary: CGI-S (Clinical Global Impression - Severity) Change From Baseline to the End of the Double-blind Treatment. [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	CGI-S (Clinical Global Impression - Severity) Change From Baseline to the End of the Double-blind Treatment.
Measure Description	The CGI-S is a clinician-rated assessment of the subject's current illness state on a 7-point scale, where a higher score is associated with greater illness severity.
Time Frame	6 weeks
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.
The primary population for the efficacy analysis was the Intent-to-Treat (ITT) population. All subjects who were randomized, received at least one dose of study medication, and have a Baseline efficacy measurement and at least one post-Baseline efficacy measurement, were in the efficacy analysis in the treatment group to which they were randomized.

Reporting Groups

	Description
40mg	Lurasidone 40 mg tablet taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 40 mg treatment group did not take any study medication.
120mg	3 40 mg tablets taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 120 mg treatment group did not take any study medication.
15mg Olz	3 5 mg Olanzapine over-encapsulated capsules taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 15 mg Olanzapine treatment group did not take any study medication.
Placebo	Placebo to match lurasidone 40mg (tablets or placebo to match olanzapine 5 mg (over-encapsulated).

Measured Values

	40mg	120mg	15mg Olz	Placebo
Overall Participants [units: participants]	**119**	**118**	**122**	**114**
CGI-S (Clinical Global Impression - Severity) Change From Baseline to the End of the Double-blind Treatment. [units: scale] Least Squares Mean (95% Confidence Interval)	**-1.5** **(-1.7 to -1.3)**	**-1.4** **(-1.6 to -1.2)**	**-1.5** **(-1.7 to -1.4)**	**-1.1** **(-1.3 to -0.9)**

Statistical Analysis 1 for CGI-S (Clinical Global Impression - Severity) Change From Baseline to the End of the Double-blind Treatment.

Groups [1]	40mg vs. 120mg vs. Placebo
Method [2]	Mixed Models Analysis
P Value [3]	<0.05

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
40mg	Lurasidone 40 mg tablet taken orally once a day. The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (478). The number of subjects in the baseline characteristics is based on the safety population (475). All randomized subjects who received at least one dose of study medication were included in the safety analysis. One subject who was randomized to the 40 mg treatment group did not take any study medication.
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Placebo	Placebo to match lurasidone 40mg (tablets or placebo to match olanzapine 5 mg (over-encapsulated).

Serious Adverse Events

	40mg	120mg	15mg Olz	Placebo
Total, serious adverse events				

# participants affected / at risk	2/119 (1.68%)	6/118 (5.08%)	5/122 (4.10%)	5/116 (4.31%)
Cardiac disorders				
Acute Myocardial Infarction				
# participants affected / at risk	0/119 (0.00%)	0/118 (0.00%)	0/122 (0.00%)	1/116 (0.86%)
Angina Pectoris				
# participants affected / at risk	0/119 (0.00%)	0/118 (0.00%)	0/122 (0.00%)	1/116 (0.86%)
Sinus Tachycardia				
# participants affected / at risk	0/119 (0.00%)	0/118 (0.00%)	1/122 (0.82%)	0/116 (0.00%)
Gastrointestinal disorders				
Heamatemesis				
# participants affected / at risk	0/119 (0.00%)	0/118 (0.00%)	0/122 (0.00%)	1/116 (0.86%)
Hepatobiliary disorders				
Hepatitis				
# participants affected / at risk	0/119 (0.00%)	0/118 (0.00%)	1/122 (0.82%)	0/116 (0.00%)
Infections and infestations				
Bronchopneumonia				
# participants affected / at risk	0/119 (0.00%)	0/118 (0.00%)	1/122 (0.82%)	0/116 (0.00%)
Psychiatric disorders				
Agitation				
# participants affected / at risk	1/119 (0.84%)	0/118 (0.00%)	0/122 (0.00%)	1/116 (0.86%)
Panic Attack				
# participants affected / at risk	0/119 (0.00%)	0/118 (0.00%)	0/122 (0.00%)	1/116 (0.86%)
Psychotic Disorder				
# participants affected / at risk	0/119 (0.00%)	4/118 (3.39%)	1/122 (0.82%)	1/116 (0.86%)
Schizophrenia				
# participants affected / at risk	1/119 (0.84%)	2/118 (1.69%)	1/122 (0.82%)	0/116 (0.00%)
Substance Abuse				
# participants affected / at risk	1/119 (0.84%)	0/118 (0.00%)	0/122 (0.00%)	0/116 (0.00%)
Suicidal Ideation				
# participants affected / at risk	1/119 (0.84%)	1/118 (0.85%)	1/122 (0.82%)	0/116 (0.00%)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
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Placebo	Placebo to match lurasidone 40mg (tablets or placebo to match olanzapine 5 mg (over-encapsulated).

Other Adverse Events

	40mg	120mg	15mg Olz	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**90/119 (75.63%)**	**96/118 (81.36%)**	**98/122 (80.33%)**	**84/116 (72.41%)**
Gastrointestinal disorders				
Constipation				
# participants affected / at risk	**6/119 (5.04%)**	**9/118 (7.63%)**	**8/122 (6.56%)**	**6/116 (5.17%)**
Dry Mouth				
# participants affected / at risk	**2/119 (1.68%)**	**3/118 (2.54%)**	**12/122 (9.84%)**	**1/116 (0.86%)**
Dyspepsia				
# participants affected / at risk	**9/119 (7.56%)**	**9/118 (7.63%)**	**5/122 (4.10%)**	**7/116 (6.03%)**
Nausea				
# participants affected / at risk	**13/119 (10.92%)**	**9/118 (7.63%)**	**6/122 (4.92%)**	**5/116 (4.31%)**
Salivary Hypersecretion				
# participants affected / at risk	**2/119 (1.68%)**	**8/118 (6.78%)**	**1/122 (0.82%)**	**0/116 (0.00%)**
Tootache				
# participants affected / at risk	**4/119 (3.36%)**	**3/118 (2.54%)**	**12/122 (9.84%)**	**6/116 (5.17%)**
Vomiting				
# participants affected / at risk	**5/119 (4.20%)**	**10/118 (8.47%)**	**2/122 (1.64%)**	**8/116 (6.90%)**
Investigations				
Weight Increased				
# participants affected / at risk	**2/119 (1.68%)**	**2/118 (1.69%)**	**25/122 (20.49%)**	**6/116 (5.17%)**
Metabolism and nutrition disorders				
Decreased Appetite				
# participants affected / at risk	**6/119 (5.04%)**	**1/118 (0.85%)**	**2/122 (1.64%)**	**2/116 (1.72%)**
Increased Appetite				
# participants affected / at risk	**1/119 (0.84%)**	**3/118 (2.54%)**	**7/122 (5.74%)**	**4/116 (3.45%)**
Musculoskeletal and connective tissue disorders				
Back Pain				
# participants affected / at risk	**6/119 (5.04%)**	**6/118 (5.08%)**	**7/122 (5.74%)**	**4/116 (3.45%)**
Musculoskeletal Stiffness				
# participants affected / at risk	**3/119 (2.52%)**	**6/118 (5.08%)**	**3/122 (2.46%)**	**2/116 (1.72%)**
Nervous system disorders				
Akathisia				
# participants affected / at risk	**14/119 (11.76%)**	**27/118 (22.88%)**	**9/122 (7.38%)**	**1/116 (0.86%)**
Dizziness				
# participants affected / at risk	**5/119 (4.20%)**	**6/118 (5.08%)**	**3/122 (2.46%)**	**2/116 (1.72%)**
Dystonia				
# participants affected / at risk	**4/119 (3.36%)**	**9/118 (7.63%)**	**1/122 (0.82%)**	**1/116 (0.86%)**
Headache				
# participants affected / at risk	**26/119 (21.85%)**	**21/118 (17.80%)**	**17/122 (13.93%)**	**25/116 (21.55%)**
Parkinsonism				
# participants affected / at risk	**11/119 (9.24%)**	**13/118 (11.02%)**	**6/122 (4.92%)**	**2/116 (1.72%)**
Sedation				
# participants affected / at risk	**11/119 (9.24%)**	**16/118 (13.56%)**	**17/122 (13.93%)**	**4/116 (3.45%)**
Somnolence				

# participants affected / at risk	**11/119 (9.24%)**	**18/118 (15.25%)**	**11/122 (9.02%)**	**5/116 (4.31%)**
Tremor				
# participants affected / at risk	**2/119 (1.68%)**	**9/118 (7.63%)**	**7/122 (5.74%)**	**5/116 (4.31%)**
Psychiatric disorders				
Agitation				
# participants affected / at risk	**13/119 (10.92%)**	**7/118 (5.93%)**	**8/122 (6.56%)**	**6/116 (5.17%)**
Anxiety				
# participants affected / at risk	**12/119 (10.08%)**	**12/118 (10.17%)**	**7/122 (5.74%)**	**8/116 (6.90%)**
Insomnia				
# participants affected / at risk	**15/119 (12.61%)**	**14/118 (11.86%)**	**13/122 (10.66%)**	**13/116 (11.21%)**
Psychotic Disorder				
# participants affected / at risk	**2/119 (1.68%)**	**0/118 (0.00%)**	**3/122 (2.46%)**	**7/116 (6.03%)**
Restlessness				
# participants affected / at risk	**6/119 (5.04%)**	**4/118 (3.39%)**	**4/122 (3.28%)**	**3/116 (2.59%)**

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:** For multi-center studies, it is mandatory that the first publication is based on all data obtained from all analyses as stipulated in the protocol. Investigators participating in multicenter studies must agree not to present data gathered individually or by subgroup of centers before the full, initial publication, unless this has been agreed to by all other investigators and also by Sunovion.

Results Point of Contact:

Name/Title: Josephine Cucchiaro, Executive Director
Organization: Sunovion Pharmacetuicals Inc.
phone: 201-592-2050
e-mail: josephine.cucchiaro@sunovion.com

Publications of Results:

Stahl SM, Cucchiaro J, Simonelli D, Hsu J, Pikalov A, Loebel A. Effectiveness of lurasidone for patients with schizophrenia following 6 weeks of acute treatment with lurasidone, olanzapine, or placebo: a 6-month, open-label, extension study. J Clin Psychiatry. 2013 May;74(5):507-15. doi: 10.4088/JCP.12m08084.

Other Publications:

Meltzer HY, Cucchiaro J, Silva R, Ogasa M, Phillips D, Xu J, Kalali AH, Schweizer E, Pikalov A, Loebel A. Lurasidone in the treatment of schizophrenia: a randomized, double-blind, placebo- and olanzapine-controlled study. Am J Psychiatry. 2011 Sep;168(9):957-67. doi: 10.1176/appi.ajp.2011.10060907.

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

Nasrallah HA, Cucchiaro JB, Mao Y, Pikalov AA, Loebel AD. Lurasidone for the treatment of depressive symptoms in schizophrenia: analysis of 4 pooled, 6-week, placebo-controlled studies. CNS Spectr. 2015 Apr;20(2):140-7. doi: 10.1017/S1092852914000285.

Responsible Party:	Sunovion
ClinicalTrials.gov Identifier:	NCT00615433 History of Changes
Other Study ID Numbers:	D**1050231**
Study First Received:	February 1, 2008
Results First Received:	November 8, 2010
Last Updated:	May 19, 2015
Health Authority:	United States: Food and Drug Administration