Trial record **1 of 1** for: 1050229
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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:
NCT00549718

First received: October 24, 2007
Last updated: June 5, 2014
Last verified: June 2014
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, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Schizophrenia
Intervention:	Drug: Lurasidone HCl

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
Lurasidone 40mg	Lurasidone 40 mg tablets taken once a day The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (500). The number of subjects in the baseline characteristics is based on the safety population (489). All randomized subjects who received at least one dose of study medication were included in the safety analysis. This means that 3 subjects were randomized but never received a dose of study drug.
Lurasidone 80mg	lurasidone 40m mg tablets taken once/day The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (500). The number of subjects in the baseline characteristics is based on the safety population (489). All randomized subjects who received at least one dose of study medication were included in the safety analysis. This means that 4 subjects were randomized but never received a dose of study drug.
Lurasidone 120mg	Lurasidone 40 mg tablets taken once/day

Placebo	Matching placebo to Lurasidone 40 mg taken once/day The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (500). The number of subjects in the baseline characteristics is based on the safety population (489). All randomized subjects who received at least one dose of study medication were included in the safety analysis. This means that 4 subjects were randomized but never received a dose of study drug.

Participant Flow: Overall Study

	Lurasidone 40mg	Lurasidone 80mg	Lurasidone 120mg	Placebo
STARTED	125	123	124	128
COMPLETED	84	86	85	73
NOT COMPLETED	41	37	39	55
Insufficient clinical response	20	7	18	32
Adverse Event	6	8	7	3
Lost to Follow-up	4	2	0	6
Withdrawal by Subject	9	18	12	13
Administrative	2	2	2	1

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
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Total	Total of all reporting groups

Baseline Measures

	Lurasidone 40mg	Lurasidone 80mg	Lurasidone 120mg	Placebo	Total
Overall Participants [units: participants]	122	119	124	124	489
Age [units: years] Mean (Standard Deviation)	40.7 (11.1)	38.6 (9.5)	37.7 (11.2)	38.2 (9.9)	38.8 (10.5)
Gender [units: participants]					
Female	40	43	32	34	149

Male	**82**	**76**	**92**	**90**	**340**
Region of Enrollment [units: participants]					
France	**0**	**1**	**1**	**1**	**3**
United States	**70**	**64**	**70**	**67**	**271**
Malaysia	**2**	**2**	**2**	**2**	**8**
Ukraine	**13**	**12**	**12**	**14**	**51**
Romania	**9**	**9**	**9**	**9**	**36**
Russian Federation	**14**	**15**	**13**	**15**	**57**
India	**14**	**16**	**17**	**16**	**63**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Total PANSS Score From Baseline to the End of the Double Blind Phase [Time Frame: 6 weeks]

Measure Type	Primary
Measure Title	Change in Total PANSS Score From Baseline to the End of the Double Blind Phase
Measure Description	The PANSS is a 30-item scale (range 30-210) designed to assess various symptoms of schizophrenia including delusions, grandiosity, blunted affect, poor attention, and poor impulse control. The 30 symptoms are rated on a 7-point scale that ranges from 1 (absent) to 7 (extreme psychopathology). The PANSS total score consists of the sum of all 30 PANSS items. Higher scores indicate worsening.
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
Lurasidone 40mg	Lurasidone 40 mg tablets taken once a day The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (500). The number of subjects in the baseline characteristics is based on the safety population (489). All randomized subjects who received at least one dose of study medication were included in the safety analysis. This means that 3 subjects were randomized but never received a dose of study drug.
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Placebo	Matching placebo to Lurasidone 40 mg taken once/day The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (500). The number of subjects in the baseline characteristics is based on the safety population (489). All randomized subjects who received at least one dose of study medication were included in the safety analysis. This means that 4 subjects were randomized but never received a dose of study drug.

Measured Values

	Lurasidone 40mg	**Lurasidone 80mg**	**Lurasidone 120mg**	**Placebo**
	121	**118**	**123**	**124**

Overall Participants [units: participants]				
Change in Total PANSS Score From Baseline to the End of the Double Blind Phase [units: scores on a scale] Least Squares Mean (95% Confidence Interval)	**-19.2** **(-22.6 to -15.7)**	**-23.4** **(-26.9 to -19.9)**	**-20.5** **(-24.0 to -17.1)**	**-17.0** **(-20.5 to -13.6)**

Statistical Analysis 1 for Change in Total PANSS Score From Baseline to the End of the Double Blind Phase

Groups [1]	All groups
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.

2. Secondary: CGI-S From Baseline to the End of the Double-blind Treatment [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	CGI-S From Baseline to the End of the Double-blind Treatment
Measure Description	Clinical Global Impression of Severity 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. The scale has a single item measured on a 7 point scale from 1 (‘normal’, not ill) to 7 (extremely ill).
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
Lurasidone 40mg	Lurasidone 40 mg tablets taken once a day The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (500). The number of subjects in the baseline characteristics is based on the safety population (489). All randomized subjects who received at least one dose of study medication were included in the safety analysis. This means that 3 subjects were randomized but never received a dose of study drug.
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Lurasidone 120mg	Lurasidone 40 mg tablets taken once/day

Placebo	Matching placebo to Lurasidone 40 mg taken once/day The number of subjects in the participant flow (overall study) is based on the total number of subjects randomized (500). The number of subjects in the baseline characteristics is based on the safety population (489). All randomized subjects who received at least one dose of study medication were included in the safety analysis. This means that 4 subjects were randomized but never received a dose of study drug.

Measured Values

	Lurasidone 40mg	Lurasidone 80mg	Lurasidone 120mg	Placebo
Overall Participants [units: participants]	**122**	**119**	**124**	**124**
CGI-S From Baseline to the End of the Double-blind Treatment [units: scores on a scale] Least Squares Mean (95% Confidence Interval)	**-1.1** **(-1.3 to -0.9)**	**-1.4** **(-1.6 to -1.2)**	**-1.2** **(-1.4 to -1.0)**	**-1.0** **(-1.2 to -0.8)**

Statistical Analysis 1 for CGI-S From Baseline to the End of the Double-blind Treatment

Groups [1]	All groups
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	14 days post study therapy
Additional Description	No text entered.

Reporting Groups

	Description
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Serious Adverse Events

	Lurasidone 40mg	Lurasidone 80mg	Lurasidone 120mg	Placebo
Total, serious adverse events				
# participants affected / at risk	**2/124 (1.61%)**	**3/121 (2.48%)**	**6/124 (4.84%)**	**5/127 (3.94%)**
Hepatobiliary disorders				
Cholecystitis [1]				
# participants affected / at risk	**0/124 (0.00%)**	**0/121 (0.00%)**	**0/124 (0.00%)**	**1/127 (0.79%)**
Infections and infestations				
Staphylococcal Infection [1]				
# participants affected / at risk	**0/124 (0.00%)**	**1/121 (0.83%)**	**0/124 (0.00%)**	**0/127 (0.00%)**
Investigations				
Blood Lactate Dehydrogenase Increased [1]				
# participants affected / at risk	**0/124 (0.00%)**	**0/121 (0.00%)**	**0/124 (0.00%)**	**1/127 (0.79%)**
Nervous system disorders				
Complex Partial Seizures [1]				
# participants affected / at risk	**1/124 (0.81%)**	**0/121 (0.00%)**	**0/124 (0.00%)**	**0/127 (0.00%)**
Psychiatric disorders				
Psychotic Disorders [1]				
# participants affected / at risk	**0/124 (0.00%)**	**1/121 (0.83%)**	**1/124 (0.81%)**	**3/127 (2.36%)**
Schizophrenia [1]				
# participants affected / at risk	**1/124 (0.81%)**	**1/121 (0.83%)**	**5/124 (4.03%)**	**1/127 (0.79%)**

1 Term from vocabulary, MedDRA (10.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	14 days post study therapy
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
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Other Adverse Events

	Lurasidone 40mg	Lurasidone 80mg	Lurasidone 120mg	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**96/124 (77.42%)**	**90/121 (74.38%)**	**106/124 (85.48%)**	**85/127 (66.93%)**
Gastrointestinal disorders				
Dyspepsia [1]				
# participants affected / at risk	**6/124 (4.84%)**	**7/121 (5.79%)**	**12/124 (9.68%)**	**6/127 (4.72%)**
Nausea [1]				
# participants affected / at risk	**14/124 (11.29%)**	**8/121 (6.61%)**	**15/124 (12.10%)**	**9/127 (7.09%)**
Vomiting [1]				
# participants affected / at risk	**5/124 (4.03%)**	**7/121 (5.79%)**	**12/124 (9.68%)**	**5/127 (3.94%)**
Investigations				
Weight Increase [1]				
# participants affected / at risk	**6/124 (4.84%)**	**4/121 (3.31%)**	**9/124 (7.26%)**	**3/127 (2.36%)**
Musculoskeletal and connective tissue disorders				
Back Pain [1]				
# participants affected / at risk	**3/124 (2.42%)**	**7/121 (5.79%)**	**2/124 (1.61%)**	**2/127 (1.57%)**
Nervous system disorders				
Akathisia [1]				
# participants affected / at risk	**14/124 (11.29%)**	**21/121 (17.36%)**	**30/124 (24.19%)**	**65/127 (51.18%)**
Dystonia [1]				
# participants affected / at risk	**6/124 (4.84%)**	**9/121 (7.44%)**	**3/124 (2.42%)**	**1/127 (0.79%)**
Headache [1]				
# participants affected / at risk	**23/124 (18.55%)**	**16/121 (13.22%)**	**21/124 (16.94%)**	**20/127 (15.75%)**
Parkinsonism [1]				
# participants affected / at risk	**8/124 (6.45%)**	**5/121 (4.13%)**	**12/124 (9.68%)**	**0/127 (0.00%)**
Sedation [1]				
# participants affected / at risk	**7/124 (5.65%)**	**13/121 (10.74%)**	**13/124 (10.48%)**	**6/127 (4.72%)**
Somnolence [1]				
# participants affected / at risk	**13/124 (10.48%)**	**12/121 (9.92%)**	**18/124 (14.52%)**	**7/127 (5.51%)**
Psychiatric disorders				
Agitation [1]				
# participants affected / at risk	**7/124 (5.65%)**	**3/121 (2.48%)**	**7/124 (5.65%)**	**2/127 (1.57%)**
Insomnia [1]				
# participants affected / at risk	**8/124 (6.45%)**	**9/121 (7.44%)**	**6/124 (4.84%)**	**10/127 (7.87%)**

1 Term from vocabulary, MedDRA (10.0)

Limitations and Caveats

Show Limitations and Caveats

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 DSP-Sepracor.

Results Point of Contact:

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

Publications of Results:

Nasrallah HA, Silva R, Phillips D, Cucchiaro J, Hsu J, Xu J, Loebel A. Lurasidone for the treatment of acutely psychotic patients with schizophrenia: a 6-week, randomized, placebo-controlled study. J Psychiatr Res. 2013 May;47(5):670-7. doi: 10.1016/j.jpsychires.2013.01.020.

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:	NCT00549718 History of Changes
Other Study ID Numbers:	D**1050229**
	2007-003819-31 (EudraCT Number)
Study First Received:	October 24, 2007
Results First Received:	November 8, 2010
Last Updated:	June 5, 2014
Health Authority:	United States: Food and Drug Administration