ClinicalTrials.gov

Try our beta test site

IMPORTANT: Listing of a study on this site does not reflect endorsement by the National Institutes of Health. Talk with a trusted healthcare professional before volunteering for a study. Read more...

Trial record **1 of 1** for: 1050233

Previous Study | Return to List | Next Study

Lurasidone HCL - A 6-week Phase 3 Study of Patients With Acute Schizophrenia. (PEARL 3)

This study has been completed.

Sponsor:
Sunovion

Information provided by (Responsible Party):
Sunovion

ClinicalTrials.gov Identifier:
NCT00790192

First received: November 10, 2008
Last updated: March 11, 2016
Last verified: March 2016
History of Changes

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

Results First Received: September 1, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Participant, Investigator); Primary Purpose: Treatment
Condition:	Schizophrenia
Interventions:	Drug: Lurasidone Drug: Quetiapine XR 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
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 80 mg	Lurasidone 80 mg tablets taken orally once a day
Lurasidone 160 mg	Lurasidone 160 mg (4 tablets) taken orally once a day
Quetiapine XR 600mg	Quetiapine XR 600 mg (4 tablets) orally taken once a day
Placebo	Matching placebo to either lurasidone or quetiapine XR. The total for this group is 73 and the adverse events only add up to 69 because the total is based on all treatment emergent adverse events not limited to >= 5%.

Participant Flow: Overall Study

	Lurasidone 80 mg	Lurasidone 160 mg	Quetiapine XR 600mg	Placebo
STARTED	125	121	120	122
COMPLETED	89	93	97	74
NOT COMPLETED	36	28	23	48

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
Lurasidone 80 mg	Lurasidone 80 mg tablets taken orally once a day
Lurasidone 160 mg	Lurasidone 160 mg (4 tablets) taken orally once a day
Quetiapine XR 600mg	Quetiapine XR 600 mg (4 tablets) orally taken once a day
Placebo	Matching placebo to either lurasidone or quetiapine XR. The total for this group is 73 and the adverse events only add up to 69 because the total is based on all treatment emergent adverse events not limited to >= 5%.
Total	Total of all reporting groups

Baseline Measures

	Lurasidone 80 mg	Lurasidone 160 mg	Quetiapine XR 600mg	Placebo	Total
Overall Participants Analyzed [Units: Participants]	125	121	120	122	488
Age [Units: Years] Mean (Standard Deviation)	36.2 (10.9)	37.9 (11.3)	37.4 (10.4)	37.4 (10.8)	37.2 (10.8)
Gender [1] [Units: Participants]					
Female	29	39	42	44	154
Male	96	82	77	77	332
[1] There were two subjects, one randomized to the Quetiapine 600 mg group and one subject randomized to placebo that did not take study drug. Thus you see a discrepancy between the participant population and the overall baseline population for the two treatment groups (1 less patient in each treatment arm).					
Region of Enrollment [1] [Units: Participants]					
United States	40	37	35	39	151
Ukraine	19	20	19	17	75
Romania	13	11	13	12	49
Russian Federation	22	22	21	22	87
India	24	25	25	24	98
Colombia	7	6	6	7	26
[1]					

There were two subjects, one randomized to the Quetiapine 600 mg group and one subject randomized to placebo that did not take study drug. Thus you see a discrepancy between the participant population and the overall baseline population(1 less patient in each treatment arm).

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Primary Efficacy Endpoint: Mean Change in Total PANSS Score From Baseline to the End of the Double Blind Phase
Measure Description	The PANSS (Positive and Negative Syndrome Scale) 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	Week 6

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 80 mg	Lurasidone 80 mg tablets taken orally once a day
Lurasidone 160 mg	Lurasidone 160 mg (4 tablets) taken orally once a day
Quetiapine XR 600mg	Quetiapine XR 600 mg (4 tablets) orally taken once a day
Placebo	Matching placebo to either lurasidone or quetiapine XR. The total for this group is 73 and the adverse events only add up to 69 because the total is based on all treatment emergent adverse events not limited to >= 5%.

Measured Values

	Lurasidone 80 mg	**Lurasidone 160 mg**	**Quetiapine XR 600mg**	**Placebo**
Participants Analyzed [Units: Participants]	**125**	**121**	**116**	**120**
Primary Efficacy Endpoint: Mean 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)	**-22.2** **(-25.7 to -18.7)**	**-26.5** **(-30.0 to -23.0)**	**-27.8** **(-31.3 to -24.2)**	**-10.3** **(-13.9 to -6.7)**

Statistical Analysis 1 for Primary Efficacy Endpoint: Mean Change in Total PANSS Score From Baseline to the End of the Double Blind Phase

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Analysis
P Value [4]	<0.05

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] 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: Secondary Outcome: CGI-S From Baseline to the End of the Double-blind Treatment [Time Frame: 6-Weeks]

Measure Type	Secondary
Measure Title	Secondary Outcome: 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

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
Lurasidone 80 mg	Lurasidone 80 mg tablets taken orally once a day
Lurasidone 160 mg	Lurasidone 160 mg (4 tablets) taken orally once a day
Quetiapine XR 600mg	Quetiapine XR 600 mg (4 tablets) orally taken once a day
Placebo	Matching placebo to either lurasidone or quetiapine XR. The total for this group is 73 and the adverse events only add up to 69 because the total is based on all treatment emergent adverse events not limited to >= 5%.

Measured Values

	Lurasidone 80 mg	**Lurasidone 160 mg**	**Quetiapine XR 600mg**	**Placebo**
Participants Analyzed [Units: Participants]	**125**	**121**	**116**	**120**
Secondary Outcome: CGI-S From Baseline to the End of the Double-blind Treatment [Units: Scores on a scale] Least Squares Mean (95% Confidence Interval)	**-1.5** **(-1.7 to -1.3)**	**-1.7** **(-1.9 to -1.5)**	**-1.7** **(-1.9 to -1.5)**	**-0.9** **(-1.1 to -0.7)**

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

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Analysis
P Value [4]	<0.05

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] 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
Lurasidone 80 mg	Lurasidone 80 mg tablets taken orally once a day
Lurasidone 160 mg	Lurasidone 160 mg (4 tablets) taken orally once a day
Quetiapine XR 600mg	Quetiapine XR 600 mg (4 tablets) orally taken once a day
Placebo	Matching placebo to either lurasidone or quetiapine XR. The total for this group is 73 and the adverse events only add up to 69 because the total is based on all treatment emergent adverse events not limited to >= 5%.

Serious Adverse Events

	Lurasidone 80 mg	Lurasidone 160 mg	Quetiapine XR 600mg	Placebo
Total, Serious Adverse Events				
# participants affected / at risk	**1/125 (0.80%)**	**4/121 (3.31%)**	**1/119 (0.84%)**	**4/121 (3.31%)**
Cardiac disorders				
Left Ventricular Dysfunction †				
# participants affected / at risk	**1/125 (0.80%)**	**4/121 (3.31%)**	**1/119 (0.84%)**	**4/121 (3.31%)**
# events	**1**	**4**	**1**	**4**
Gastrointestinal disorders				
Abdominal Hernia Obstructive †				
# participants affected / at risk	**0/125 (0.00%)**	**1/121 (0.83%)**	**0/119 (0.00%)**	**0/121 (0.00%)**
# events	**0**	**1**	**0**	**0**
General disorders				
Non-cardiac Chest Pain †				
# participants affected / at risk	**0/125 (0.00%)**	**1/121 (0.83%)**	**0/119 (0.00%)**	**0/121 (0.00%)**
# events	**0**	**1**	**0**	**0**
Infections and infestations				
Hepatitis Viral †				
# participants affected / at risk	**0/125 (0.00%)**	**0/121 (0.00%)**	**1/119 (0.84%)**	**0/121 (0.00%)**
# events	**0**	**0**	**119**	**0**
Injury, poisoning and procedural complications				
Hand Fracture †				
# participants affected / at risk	**0/125 (0.00%)**	**1/121 (0.83%)**	**0/119 (0.00%)**	**0/121 (0.00%)**
# events	**0**	**1**	**0**	**0**

Psychiatric disorders				
Agression †				
# participants affected / at risk	**0/125 (0.00%)**	**0/121 (0.00%)**	**0/119 (0.00%)**	**1/121 (0.83%)**
# events	**0**	**0**	**0**	**1**
Pyschotic Disorder †				
# participants affected / at risk	**0/125 (0.00%)**	**0/121 (0.00%)**	**1/119 (0.84%)**	**2/121 (1.65%)**
# events	**0**	**0**	**1**	**2**
Schizophrenia †				
# participants affected / at risk	**0/125 (0.00%)**	**1/121 (0.83%)**	**0/119 (0.00%)**	**0/121 (0.00%)**
# events	**0**	**1**	**0**	**0**
Suicidal Behavior †				
# participants affected / at risk	**0/125 (0.00%)**	**0/121 (0.00%)**	**0/119 (0.00%)**	**1/121 (0.83%)**
# events	**0**	**0**	**0**	**1**
Suicidal Ideation †				
# participants affected / at risk	**0/125 (0.00%)**	**0/121 (0.00%)**	**0/119 (0.00%)**	**2/121 (1.65%)**
# events	**0**	**0**	**0**	**2**
Social circumstances				
Physical Assault †				
# participants affected / at risk	**1/125 (0.80%)**	**0/121 (0.00%)**	**0/119 (0.00%)**	**0/121 (0.00%)**
# events	**1**	**0**	**0**	**0**
Vascular disorders				
Labile Hypertension †				
# participants affected / at risk	**0/125 (0.00%)**	**1/121 (0.83%)**	**0/119 (0.00%)**	**0/121 (0.00%)**
# events	**0**	**1**	**0**	**0**

† Events were collected by systematic assessment

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
Lurasidone 80 mg	Lurasidone 80 mg tablets taken orally once a day
Lurasidone 160 mg	Lurasidone 160 mg (4 tablets) taken orally once a day
Quetiapine XR 600mg	Quetiapine XR 600 mg (4 tablets) orally taken once a day
Placebo	Matching placebo to either lurasidone or quetiapine XR. The total for this group is 73 and the adverse events only add up to 69 because the total is based on all treatment emergent adverse events not limited to >= 5%.

Other Adverse Events

	Lurasidone 80 mg	**Lurasidone 160 mg**	**Quetiapine XR 600mg**	**Placebo**
Total, Other (not including serious) Adverse Events				
# participants affected / at risk	**71/125 (56.80%)**	**76/121 (62.81%)**	**70/119 (58.82%)**	**69/121 (57.02%)**
Gastrointestinal disorders				

Constipation †				
# participants affected / at risk	3/125 (2.40%)	1/121 (0.83%)	8/119 (6.72%)	3/121 (2.48%)
# events	3	1	8	3
Dry Mouth †				
# participants affected / at risk	2/125 (1.60%)	2/121 (1.65%)	9/119 (7.56%)	1/121 (0.83%)
# events	2	2	9	1
Dyspepsia †				
# participants affected / at risk	3/125 (2.40%)	7/121 (5.79%)	3/119 (2.52%)	4/121 (3.31%)
# events	3	7	3	4
Nausea †				
# participants affected / at risk	10/125 (8.00%)	8/121 (6.61%)	4/119 (3.36%)	4/121 (3.31%)
# events	10	8	4	4
Vomiting †				
# participants affected / at risk	8/125 (6.40%)	9/121 (7.44%)	6/119 (5.04%)	6/121 (4.96%)
# events	8	9	6	6
Infections and infestations				
Upper Respiratory Tract Infection †				
# participants affected / at risk	2/125 (1.60%)	1/121 (0.83%)	6/119 (5.04%)	1/121 (0.83%)
# events	2	1	6	1
Investigations				
Weight Increase †				
# participants affected / at risk	1/125 (0.80%)	2/121 (1.65%)	8/119 (6.72%)	1/121 (0.83%)
# events	1	2	8	1
Musculoskeletal and connective tissue disorders				
Arthralgia †				
# participants affected / at risk	2/125 (1.60%)	1/121 (0.83%)	7/119 (5.88%)	1/121 (0.83%)
# events	2	1	7	1
Nervous system disorders				
Akathisia †				
# participants affected / at risk	10/125 (8.00%)	9/121 (7.44%)	2/119 (1.68%)	1/121 (0.83%)
# events	10	9	2	1
Dizziness †				
# participants affected / at risk	6/125 (4.80%)	7/121 (5.79%)	16/119 (13.45%)	2/121 (1.65%)
# events	6	7	16	2
Headache †				
# participants affected / at risk	12/125 (9.60%)	12/121 (9.92%)	13/119 (10.92%)	13/121 (10.74%)
# events	12	12	13	13
Parkinsonism †				
# participants affected / at risk	7/125 (5.60%)	8/121 (6.61%)	4/119 (3.36%)	0/121 (0.00%)
# events	7	8	4	0
Somnolence †				
# participants affected / at risk	5/125 (4.00%)	8/121 (6.61%)	16/119 (13.45%)	1/121 (0.83%)
# events	5	8	16	1
Psychiatric disorders				
Agitation †				
# participants affected / at risk	4/125 (3.20%)	6/121 (4.96%)	3/119 (2.52%)	10/121 (8.26%)
# events	4	6	3	10
Anxiety †				
# participants affected / at risk	9/125 (7.20%)	4/121 (3.31%)	1/119 (0.84%)	10/121 (8.26%)
# events	9	4	1	10
Insomnia †				
# participants affected / at risk	14/125 (11.20%)	8/121 (6.61%)	5/119 (4.20%)	11/121 (9.09%)

# events	14	8	5	11

† Events were collected by systematic assessment

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: Josephine Cucchiaro, PhD, Executive Director
Organization: Sunovion
phone: 201-592-2050
e-mail: josephine.cucchiaro@sunovion.com

Publications of Results:

Loebel A, Cucchiaro J, Sarma K, Xu L, Hsu C, Kalali AH, Pikalov A, Potkin SG. Efficacy and safety of lurasidone 80 mg/day and 160 mg/day in the treatment of schizophrenia: a randomized, double-blind, placebo- and active-controlled trial. Schizophr Res. 2013 Apr;145(1-3):101-9. doi: 10.1016/j.schres.2013.01.009. Epub 2013 Feb 13.

Harvey PD, Siu CO, Hsu J, Cucchiaro J, Maruff P, Loebel A. Effect of lurasidone on neurocognitive performance in patients with schizophrenia: a short-term placebo- and active-controlled study followed by a 6-month double-blind extension. Eur Neuropsychopharmacol. 2013 Nov;23(11):1373-82. doi: 10.1016/j.euroneuro.2013.08.003. Epub 2013 Aug 27.

Loebel AD, Siu CO, Cucchiaro JB, Pikalov AA, Harvey PD. Daytime sleepiness associated with lurasidone and quetiapine XR: results from a randomized double-blind, placebo-controlled trial in patients with schizophrenia. CNS Spectr. 2014 Apr;19(2):197-205. doi: 10.1017/S1092852913000904. Epub 2013 Dec 13.

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

Harvey PD, Siu CO, Ogasa M, Loebel A. Effect of lurasidone dose on cognition in patients with schizophrenia: post-hoc analysis of a long-term, double-blind continuation study. Schizophr Res. 2015 Aug;166(1-3):334-8. doi: 10.1016/j.schres.2015.06.008. Epub 2015 Jun 24.

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. Epub 2014 Jun 23.

Responsible Party: Sunovion
ClinicalTrials.gov Identifier: NCT00790192 History of Changes
Other Study ID Numbers: D**1050233**
Study First Received: November 10, 2008
Results First Received: September 1, 2011
Last Updated: March 11, 2016