Clinical trial results:
A 6-Week Randomized, Parallel, Double-Blind, Placebo-Controlled, Fixed-Dose, Multicenter Study To Evaluate The Efficacy and Safety of Lurasidone in Adolescent Subjects with Schizophrenia

Summary

EudraCT number	2013-001695-38
Trial protocol	ES IT Outside EU/EEA BG HU GB BE FR RO
Global end of trial date	29 December 2015

Results information

Result version number	v1 (current)
This version publication date	31 December 2016
First version publication date	31 December 2016

Trial information

Trial identification

Sponsor protocol code	D1050301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01911429
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sunovion Pharmaceuticals Inc.
Sponsor organisation address	One Bridge Plaza North, Suite 510, Fort Lee, United States, 07024
Public contact	Medical Director, Sunovion Pharmaceuticals Inc., 001 1-866-503-6351, clinicaltrialsdisclosure@sunovion.com
Scientific contact	Medical Director, Sunovion Pharmaceuticals Inc., 001 1-866-503-6351, clinicaltrialsdisclosure@sunovion.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001230-PIP01-11
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 July 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 December 2015
Global end of trial reached?	Yes
Global end of trial date	29 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy and Safety study of Lurasidone in pediatric patients.

Protection of trial subjects:

The study was conducted according to the protocol, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), ICH guidelines, and the ethical principles that have their origin in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Colombia: 16
Country: Number of subjects enrolled	Russian Federation: 46
Country: Number of subjects enrolled	Romania: 16
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	United States: 110
Country: Number of subjects enrolled	Philippines: 6
Country: Number of subjects enrolled	Ukraine: 74
Country: Number of subjects enrolled	Malaysia: 4
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	Mexico: 10
Country: Number of subjects enrolled	Bulgaria: 24
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 5
Worldwide total number of subjects	326
EEA total number of subjects	55

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	326
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

male and female subjects 13 to 17, inclusive,with DSM-IV-TR Axis I primary diagnosis of schizophrenia and confirmation of the diagnosis by means of the Schedule for Affective Disorders and Schizophrenia for School-age Children. Positive and Negative Syndrome Scale total score >70 at screening and Baseline; CGI-S > 4 at screening and baseline.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Lurasidone 40 mg

Arm description:

Lurasidone 40 mg once daily

Arm type	Experimental
Investigational medicinal product name	lurasidone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

lurasidone 40 mg once daily

Arm title	Lurasidone 80 mg

Arm description:

Lurasidone 80 mg once daily

Lurasidone 80 mg: Lurasidone 80 mg once daily

Arm type	Experimental
Investigational medicinal product name	lurasidone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

lursidone 80mg once daily

Subjects received lurasidone 40/mg day from Days 1-3, and 80mg/day from days 4 to Week 6 visit

Arm title	Placebo

Arm description:

Placebo 40 or 80 mg once daily

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
placebo once daily

Number of subjects in period 1	Lurasidone 40 mg	Lurasidone 80 mg	Placebo
Started	108	104	112
Completed	98	92	92
Not completed	12	12	20
Consent withdrawn by subject	5	5	4
Adverse event, non-fatal	5	3	9
Transferred to other arm/group	-	2	-
accidental randomization	-	-	1
Lost to follow-up	-	-	1
Lack of efficacy	1	2	4
subject left study	1	-	-
Protocol deviation	-	-	1
Joined	2	0	0
Transferred in from other group/arm	2	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Lurasidone 40 mg
Reporting group description: Lurasidone 40 mg once daily	

Reporting group title	Lurasidone 80 mg
Reporting group description: Lurasidone 80 mg once daily	

Lurasidone 80 mg: Lurasidone 80 mg once daily

Reporting group title	Placebo
Reporting group description: Placebo 40 or 80 mg once daily	

Reporting group values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo
Number of subjects	110	104	112
Age Categorical Units: Participants			
<=18 years	110	104	112
Between 18 and 65 years	0	0	0
>=65 years	0	0	0
Age Continuous Units: years			
arithmetic mean	15.5	15.3	15.3
standard deviation	± 1.33	± 1.35	± 1.37
Gender, Male/Female Units: Participants			
Female	67	70	71
Male	43	34	41
Age, Customized Units: Subjects			
13-15 years old	50	55	55
16-17 years old	60	49	57
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	13	18	13
Not Hispanic or Latino	97	86	99
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	6	4	5
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	20	18	22
White	73	73	74

More than one race	11	9	11
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
North America	38	35	37
South America	9	8	9
Europe	57	57	61
Southeast Asia	4	3	4
East Asia	2	1	1
DSM-IV diagnosis of Schizophrenia Units: Subjects			
295.10 schizophrenia, disorganized type	13	6	7
295.30 schizophrenia, paranoid type	88	81	85
295.90 schizophrenia, undifferentiated type	9	17	20
BaselineBMI Percentile Units: Subjects			
< 3th percentile	0	1	0
> 3th to 85th percentile	74	65	72
> 85th to 97th percentile	30	32	32
> 97th percentile	6	6	8
Baseline BMI Units: units on a scale			
arithmetic mean	22.38	22.56	22.52
standard deviation	± 3.262	± 3.497	± 3.606
Baseline weight Units: units on a scale			
arithmetic mean	63.5	63.9	64
standard deviation	± 12.39	± 12.88	± 11.88

Reporting group values	Total		
Number of subjects	326		
Age Categorical Units: Participants			
<=18 years	326		
Between 18 and 65 years	0		
>=65 years	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: Participants			
Female	208		
Male	118		
Age, Customized Units: Subjects			
13-15 years old	160		
16-17 years old	166		
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	44		
Not Hispanic or Latino	282		
Unknown or Not Reported	0		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	15		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	60		
White	220		
More than one race	31		
Unknown or Not Reported	0		
Region of Enrollment			
Units: Subjects			
North America	110		
South America	26		
Europe	175		
Southeast Asia	11		
East Asia	4		
DSM-IV diagnosis of Schizophrenia			
Units: Subjects			
295.10 schizophrenia, disorganized type	26		
295.30 schizophrenia, paranoid type	254		
295.90 schizophrenia, undifferentiated type	46		
BaselineBMI Percentile			
Units: Subjects			
< 3th percentile	1		
> 3th to 85th percentile	211		
> 85th to 97th percentile	94		
> 97th percentile	20		
Baseline BMI			
Units: units on a scale			
arithmetic mean			
standard deviation	-		
Baseline weight			
Units: units on a scale			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	Lurasidone 40 mg
Reporting group description: Lurasidone 40 mg once daily	

Reporting group title	Lurasidone 80 mg
Reporting group description: Lurasidone 80 mg once daily Lurasidone 80 mg: Lurasidone 80 mg once daily	

Reporting group title	Placebo
Reporting group description: Placebo 40 or 80 mg once daily	

Primary: change from Baseline in the Positive and Negative Syndrome Scale (PANSS) total score at Week 6.

End point title	change from Baseline in the Positive and Negative Syndrome Scale (PANSS) total score at Week 6.

End point description:

PANNS total score: Changes from baseline over time - mixed model for repeated measures at week 6

LS Mean and SE for change from baseline are based on Mixed Model for Repeated Measures with fixed effects terms for treatment, visit (as a categorical variable), pooled country, age strata, PANSS total score at baseline, and treatment-by-visit interaction.

End point type	Primary

End point timeframe:

Baseline to 6 weeks

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	94.5 (± 10.97)	94 (± 11.12)	92.8 (± 11.08)	
Week 6	-18.6 (± 1.59)	-18.3 (± 1.6)	-10.5 (± 1.59)	

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE

Statistical analysis description:

The sample size was estimated to provide at least 85% power to reject at least one of the null

hypotheses of no difference between placebo and lurasidone doses.
LS Mean, LS mean difference, and the associated 95% CI and p-value for change from baseline are based on Mixed Model for Repeated Measures (MMRM).

Comparison groups	Lurasidone 40 mg v Placebo
Number of subjects included in analysis	220
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	LS mean difference (SE)
Parameter estimate	LS mean difference (SE)
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.4
upper limit	-3.7
Variability estimate	Standard deviation

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE

Statistical analysis description:

The sample size was estimated to provide at least 85% power to reject at least one of the null hypotheses of no difference between placebo and lurasidone doses.
LS Mean, LS mean difference, and the associated 95% CI and p-value for change from baseline are based on Mixed Model for Repeated Measures (MMRM).

Comparison groups	Lurasidone 80 mg v Placebo
Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	LS mean difference (SE)
Parameter estimate	LS mean difference (SE)
Point estimate	-7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.1
upper limit	-3.4
Variability estimate	Standard deviation

Secondary: Change from Baseline in Clinical Global Impression severity (CGI-S) scale at Day 4, Weeks 1, 2, 3, 4, 5, and 6

End point title	Change from Baseline in Clinical Global Impression severity (CGI-S) scale at Day 4, Weeks 1, 2, 3, 4, 5, and 6

End point description:

Clinical Global Impression severity (CGI-S): Changes from baseline over time-mixed model for repeated measures

LS Mean and SE for change from baseline are based on Mixed Model for Repeated Measures with fixed effects terms for treatment, visit (as a categorical variable), pooled country, age strata, CGIS at baseline, and treatment-by-visit interaction.

End point type	Secondary
End point timeframe: baseline, week 6	

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	4.9 (± 0.62)	4.8 (± 0.66)	4.8 (± 0.61)	
week 6	-0.97 (± 0.093)	-0.92 (± 0.093)	-0.5 (± 0.094)	

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Statistical analysis description: LS Mean, LS mean difference, and the associated 95% CI and p-value for change from baseline are based on Mixed Model for Repeated Measures (MMRM).	
Comparison groups	Lurasidone 40 mg v Placebo
Number of subjects included in analysis	220
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	LS mean difference (SE)
Parameter estimate	LS mean difference (SE)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.73
upper limit	-0.22
Variability estimate	Standard deviation

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Statistical analysis description: LS Mean, LS mean difference, and the associated 95% CI and p-value for change from baseline are based on Mixed Model for Repeated Measures (MMRM).	
Comparison groups	Lurasidone 80 mg v Placebo

Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0015
Method	LS mean difference (SE)
Parameter estimate	LS mean difference (SE)
Point estimate	-0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	-0.16
Variability estimate	Standard deviation

Secondary: Change from Baseline in PANSS total score at Day 4, Weeks 1, 2, 3, 4, and 5

End point title	Change from Baseline in PANSS total score at Day 4, Weeks 1, 2, 3, 4, and 5

End point description:

PANSS positive subscale score: changes from baseline over time - mixed model for repeated measures

LS Mean and SE for change from baseline are based on Mixed Model for Repeated Measures with fixed effects terms for treatment, visit (as a categorical variable), pooled country, age strata, corresponding PANSS subscale score at baseline, and treatment-by-visit interaction.

End point type	Secondary

End point timeframe:

baseline, week 6

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	24.1 (± 3.96)	24 (± 4.08)	23.4 (± 3.75)	
week 6	-6.3 (± 0.51)	-6.3 (± 0.51)	-3.1 (± 0.51)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PANSS positive, negative, general psychopathology, and excitability subscale scores at Day 4, Weeks 1, 2, 3, 4, 5, and 6

End point title	Change from Baseline in PANSS positive, negative, general psychopathology, and excitability subscale scores at Day 4, Weeks 1, 2, 3, 4, 5, and 6

End point description:

PANSS Negative subscale score: changes form baseline over time - Mixed model for repeated measures

LS Mean and SE for change from baseline are based on Mixed Model for Repeated Measures with fixed effects terms for treatment, visit (as a categorical variable), pooled country, age strata, corresponding PANSS subscale score at baseline, and treatment-by-visit interaction.

End point type	Secondary

End point timeframe:

baseline, week 6

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	24.2 (± 4.32)	24.5 (± 4.37)	24.4 (± 4.01)	
week 6	-4 (± 0.48)	-3.8 (± 0.49)	-2.3 (± 0.49)	

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of responders, where response is based on ≥ 20% improvement from Baseline in PANSS total score at Week 6

End point title	Proportion of responders, where response is based on ≥ 20% improvement from Baseline in PANSS total score at Week 6

End point description:

PANSS responder analysis over time: achieving >= 20% reduction from baseline

End point type	Secondary

End point timeframe:

week 6

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: number of participants				
number (not applicable)	69	47	69	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) at Week 6

End point title	Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) at Week 6

End point description:

PQ-LES-Q percentage maximum possible score: summary statistics over time

LS Mean and SE for change from baseline are from an ANCOVA model including factors of treatment, pooled country and age group (stratification factor), and corresponding Baseline score as covariate and LOCF approach.

End point type	Secondary

End point timeframe:

baseline, week 6

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	51.3 (± 17.26)	53.6 (± 18.5)	52.5 (± 15.67)	
week 6	5.6 (± 1.28)	6.1 (± 1.3)	0.3 (± 1.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinician-rated Children's Global Assessment Scale (CGAS) at Week 6

End point title	Change from Baseline in Clinician-rated Children's Global Assessment Scale (CGAS) at Week 6

End point description:

Clinician-rated Children's Global Assessment Scale (CGAS) score: summary statistics over time

LS Mean and SE for change from baseline are from an ANCOVA model including factors of treatment, pooled country and age group (stratification factor), and corresponding Baseline score as covariate and LOCF approach.

End point type	Secondary

End point timeframe:

baseline, week 6

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	44.2 (± 9.33)	44.6 (± 8.11)	43.9 (± 8.34)	
week 6	11.3 (± 1.16)	11.9 (± 1.18)	7.5 (± 1.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in PANSS general psychopathology subscale scores

End point title	Change from baseline in PANSS general psychopathology subscale scores

End point description:

PANSS general psychopathology subscale score: changes from baseline over time - mixed model for repeated measures

LS Mean and SE for change from baseline are based on Mixed Model for Repeated Measures with fixed effects terms for treatment, visit (as a categorical variable), pooled country, age strata, corresponding PANSS subscale score at baseline, and treatment-by-visit interaction.

End point type	Secondary

End point timeframe:

baseline, week 6

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	46.2 (± 6.65)	45.5 (± 7.03)	45 (± 6.94)	
week 6	-8.1 (± 0.8)	-8.1 (± 0.81)	-5.3 (± 0.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in PANSS excitability subscale scores

End point title	Change from baseline in PANSS excitability subscale scores

End point description:

LS Mean and SE for change from baseline are based on Mixed Model for Repeated Measures with fixed effects terms for treatment, visit (as a categorical variable), pooled country, age strata, corresponding PANSS subscale score at baseline, and treatment-by-visit interaction.

End point type	Secondary

End point timeframe:
baseline, week 6

End point values	Lurasidone 40 mg	Lurasidone 80 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	104	112	
Units: units on a scale				
arithmetic mean (standard deviation)				
baseline	10.8 (± 2.91)	11.1 (± 3.07)	10.7 (± 3.23)	
week 6	-0.6 (± 0.33)	-1.7 (± 0.33)	-2.4 (± 0.33)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

An AE with a start date on or after the date of first dose
through 7 days after study drug discontinuation (14 days for serious adverse events and deaths)

Adverse event reporting additional description:

AEs were collected from the time the informed consent is signed to the end of the study. Non-leading questions were used to ask subjects about the possible occurrence of AEs. The investigator then established a diagnosis of the event based on signed, symptoms, and/or other clinical information.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Lurasidone 40 mg

Reporting group description:

Lurasidone 40 mg once daily

Lurasidone 40 mg: Lurasidone 40 mg once daily

Reporting group title	Placebo

Reporting group description:

Placebo 40 or 80 mg once daily

Placebo 40 or 80 mg: Placebo 40 or 80 mg once daily

Reporting group title	Lurasidone 80 mg

Reporting group description:

Lurasidone 80 mg once daily

Lurasidone 80 mg: Lurasidone 80 mg once daily

Serious adverse events	Lurasidone 40 mg	Placebo	Lurasidone 80 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 110 (3.64%)	9 / 112 (8.04%)	2 / 104 (1.92%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 110 (0.91%)	0 / 112 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
schizophrenia			

subjects affected / exposed	2 / 110 (1.82%)	7 / 112 (6.25%)	2 / 104 (1.92%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Homicidal Ideation			
subjects affected / exposed	1 / 110 (0.91%)	0 / 112 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 110 (0.00%)	1 / 112 (0.89%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 110 (0.00%)	1 / 112 (0.89%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Lurasidone 40 mg	Placebo	Lurasidone 80 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	70 / 110 (63.64%)	53 / 112 (47.32%)	67 / 104 (64.42%)
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 110 (6.36%)	14 / 112 (12.50%)	11 / 104 (10.58%)
occurrences (all)	8	19	15
Somnolence			
subjects affected / exposed	10 / 110 (9.09%)	6 / 112 (5.36%)	12 / 104 (11.54%)
occurrences (all)	10	8	12
Sedation			
subjects affected / exposed	6 / 110 (5.45%)	2 / 112 (1.79%)	2 / 104 (1.92%)
occurrences (all)	6	2	3
Akathisia			
subjects affected / exposed	10 / 110 (9.09%)	2 / 112 (1.79%)	9 / 104 (8.65%)
occurrences (all)	12	2	10
Gastrointestinal disorders			

Nausea			
subjects affected / exposed	14 / 110 (12.73%)	3 / 112 (2.68%)	15 / 104 (14.42%)
occurrences (all)	20	4	18
Vomiting			
subjects affected / exposed	9 / 110 (8.18%)	2 / 112 (1.79%)	7 / 104 (6.73%)
occurrences (all)	10	2	8
Psychiatric disorders			
Insomnia			
subjects affected / exposed	6 / 110 (5.45%)	10 / 112 (8.93%)	7 / 104 (6.73%)
occurrences (all)	6	12	8
Agitation			
subjects affected / exposed	5 / 110 (4.55%)	5 / 112 (4.46%)	6 / 104 (5.77%)
occurrences (all)	7	5	6
Anxiety			
subjects affected / exposed	11 / 110 (10.00%)	9 / 112 (8.04%)	3 / 104 (2.88%)
occurrences (all)	14	11	3

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

none

Notes: