Clinical trial results:
Interventional, open-label, flexible-dose extension study of aripiprazole once-monthly in patients with schizophrenia

Summary

EudraCT number	2012-003239-47
Trial protocol	CZ DE ES IT EE SE FR
Global end of trial date	19 March 2015

Results information

Result version number	v1 (current)
This version publication date	03 April 2016
First version publication date	03 April 2016

Trial information

Trial identification

Sponsor protocol code	14724B

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01959035
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	H. Lundbeck A/S
Sponsor organisation address	Ottiliavej 9, Valby, Denmark, 2500
Public contact	LundbeckClinicalTrials@lundbeck.com, H. Lundbeck A/S, LundbeckClinicalTrials@lundbeck.com
Scientific contact	LundbeckClinicalTrials@lundbeck.com, H. Lundbeck A/S, LundbeckClinicalTrials@lundbeck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
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	19 March 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 March 2015
Global end of trial reached?	Yes
Global end of trial date	19 March 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To obtain information on the safety, tolerability and effectiveness of aripiprazole once-monthly in a manner consistent with its intended use in everyday clinical practice in patients with schizophrenia who completed Study 14724A / NCT01795547)

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (2008) and ICH Good Clinical Practice (1996)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 12
Country: Number of subjects enrolled	Sweden: 3
Country: Number of subjects enrolled	Czech Republic: 11
Country: Number of subjects enrolled	Estonia: 15
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Italy: 10
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	United States: 18
Worldwide total number of subjects	88
EEA total number of subjects	69

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)	0
Adults (18-64 years)	88
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects who met each of the inclusion and none of the exclusion criteria were eligible to participate in the study

Period 1

Period 1 title	Overall Period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Aripiprazole

Arm description:

Aripiprazole once-monthly: 400 or 300 mg/month; 6 intramuscular (IM) injections starting at baseline

Arm type	Experimental
Investigational medicinal product name	Aripiprazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for prolonged-release suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Aripiprazole once-monthly: 400 or 300 mg/month; 6 intramuscular (IM) injections starting at baseline

Number of subjects in period 1	Aripiprazole
Started	88
Completed	77
Not completed	11
Consent withdrawn by subject	4
Adverse event, non-fatal	5
(no primary reason given)	1
Lost to follow-up	1

Baseline characteristics

Reporting groups	
Reporting group title	Aripiprazole
Reporting group description:	
Aripiprazole once-monthly: 400 or 300 mg/month; 6 intramuscular (IM) injections starting at baseline	

Reporting group values	Aripiprazole	Total	
Number of subjects	88	88	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	43.4		
standard deviation	± 10.9	-	
Gender categorical Units: Subjects			
Female	36	36	
Male	52	52	

End points

End points reporting groups

Reporting group title	Aripiprazole

Reporting group description:

Aripiprazole once-monthly: 400 or 300 mg/month; 6 intramuscular (IM) injections starting at baseline

Primary: Number of treatment emergent adverse events (TEAEs)

End point title	Number of treatment emergent adverse events (TEAEs)[1]

End point description:

End point type	Primary

End point timeframe:

From baseline and up to 24 weeks and the 4-week safety follow-up

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses were performed, it was just a calculation

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	88			
Units: number of events	65			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in SWN-S Total Score

End point title	Change From Baseline to Week 24 in SWN-S Total Score

End point description:

The Subjective Well-Being under Neuroleptic Treatment - Short Version (SWN-S) is a patient-rated scale designed to measure subjective effects of neuroleptic drugs to psychopathology, quality of life, and compliance over the past 7 days. The 20 items (10 positive and 10 negative statements) are grouped in 5 subscales (mental functioning, selfcontrol, physical functioning, emotional regulation and social integration). Each subscale contains 4 items. Each item was rated on a six-point Likert scale, from not at all to very much. A score was calculated for each subscale, and the total score ranged from 20 to 120, where the higher score indicated better well-being.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: Units on a scale				
least squares mean (confidence interval 95%)	0.19 (-2.08 to 2.45)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in CGI-S Score

End point title	Change From Baseline to Week 24 in CGI-S Score

End point description:

Clinical Global Impression - Severity of Illness (CGI-S) score provides the clinician's impression of the patient's current state of mental illness. The clinician uses his or her clinical experience of this patient population to rate the severity of the patient's current mental illness on a 7-point scale ranging from 1 (normal - not at all ill) to 7 (among the most extremely ill patients).

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.1 (-0.26 to 0.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in QLS Total Score

End point title	Change From Baseline to Week 24 in QLS Total Score

End point description:

The Quality of Life Scale (QLS) is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). Definitions were provided for 4 anchor points of the 7 points. Each item had a brief description of the judgement to be made and a set of suggested probes for the clinician. The total score was calculated as the sum of all 21 items giving a range of 0 to 126, where the higher score indicated normal or unimpaired functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: units on a scale				
least squares mean (confidence interval 95%)	2.32 (-1.21 to 5.85)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in the 'Common Objects and Activities' QLS Domain Score

End point title	Change From Baseline to Week 24 in the 'Common Objects and Activities' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Common Objects and Activities domain score was calculated as the sum of 2 items (numbers 18 and 19) giving a range of 0 to 12, where the higher score indicated less unimpaired functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: units on a scale				
arithmetic mean (standard deviation)	0.21 (± 1.29)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in the 'Intrapsychic Foundations' QLS Domain Score

End point title	Change From Baseline to Week 24 in the 'Intrapsychic

	Foundations' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Intrapsychic Foundations domain score was calculated as the sum of 7 items (numbers 13 to 17 and 20 and 21) giving a range of 0 to 42, where the higher score indicated less unimpaired functioning

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: units on a scale				
arithmetic mean (standard error)	0.72 (± 5.03)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in the 'Interpersonal Relations' QLS Domain Score

End point title	Change From Baseline to Week 24 in the 'Interpersonal Relations' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Interpersonal Relations domain score was calculated as the sum of 8 items (numbers 1 to 8) giving a range of 0 to 48, where the higher score indicated less unimpaired functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: units on a scale				
arithmetic mean (standard deviation)	0.58 (± 6.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in the 'Instrumental Role' QLS Domain Score

End point title	Change From Baseline to Week 24 in the 'Instrumental Role' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Instrumental Role domain score was calculated as the sum of 4 items (numbers 9 to 12) giving a range of 0 to 24, where the higher score indicated less unimpaired functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: units on a scale				
arithmetic mean (standard deviation)	0.42 (± 4.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in the TooL Total Score

End point title	Change From Baseline to Week 24 in the TooL Total Score

End point description:

Tolerability and Quality of Life (TooL) is a patient-rated scale developed to measure the impact of side-effects on the quality of life in patients treated with antipsychotic medication. The TooL consists of 8 domains: mood (worry-upset), function capabilities, fatigue-weakness, weight gain, stiffness-tremor, physical restlessness, sexual dysfunction, and dizziness-nausea. Each domain was rated on a four-point scale from 1 (no impact) to 4 (maximum impact). Total scores ranged from 8 (no impact) to 32 (maximum impact).

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.47 (-1.16 to 0.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in ASEX Total Score

End point title	Change From Baseline to Week 24 in ASEX Total Score

End point description:

The Arizona Sexual Experience Scale (ASEX) is a five-item, patient-rated scale that evaluates a patient's recent sexual experiences. The ASEX is used to identify individuals with sexual dysfunction. Patients were asked to assess their own experiences over the last week (for example, "How strong is your sex drive?", "Are your orgasms satisfying?") and respond on a six-point scale for each item. Possible total scores range from 5 to 30. Higher ASEX total scores indicate more sexual dysfunction (hypofunction).

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.42 (-1.74 to 0.91)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in the WoRQ Total Score

End point title	Change From Baseline to Week 24 in the WoRQ Total Score

End point description:

The Readiness for Work Questionnaire (WoRQ) is a clinician-rated scale designed to measure a schizophrenic patient's ability to work. The WoRQ consists of 8 items: the clinician had to rate 7 statements and answer 1 question. The statements were rated on a four-point scale, from 'strongly agree', 'agree', 'disagree' or 'strongly disagree' based on all material available (for example, personal notes, medical records, input from other health professionals, family members or caregivers); and in the

final item, the clinician had to indicate if the patient was ready for work or not (by indicating either 'yes' or 'no'). Lower WoRQ total scores indicate better functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.53 (-1.21 to 0.15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in SWN-S Total Score

End point title	Change From Baseline to Week 12 in SWN-S Total Score

End point description:

The Subjective Well-Being under Neuroleptic Treatment - Short Version (SWN-S) is a patient-rated scale designed to measure subjective effects of neuroleptic drugs to psychopathology, quality of life, and compliance over the past 7 days. The 20 items (10 positive and 10 negative statements) are grouped in 5 subscales (mental functioning, selfcontrol, physical functioning, emotional regulation and social integration). Each subscale contains 4 items. Each item was rated on a six-point Likert scale, from not at all to very much. A score was calculated for each subscale, and the total score ranged from 20 to 120, where the higher score indicated better well-being.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: Units on a scale				
least squares mean (confidence interval 95%)	-1.57 (-4.19 to 1.05)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in CGI-S Score

End point title	Change From Baseline to Week 12 in CGI-S Score

End point description:

Clinical Global Impression - Severity of Illness (CGI-S) score provides the clinician's impression of the patient's current state of mental illness. The clinician uses his or her clinical experience of this patient population to rate the severity of the patient's current mental illness on a 7-point scale ranging from 1 (normal - not at all ill) to 7 (among the most extremely ill patients).

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	83			
Units: units on a scale				
least squares mean (confidence interval 95%)	0 (-0.14 to 0.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in QLS Total Score

End point title	Change From Baseline to Week 12 in QLS Total Score

End point description:

The Quality of Life Scale (QLS) is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). Definitions were provided for 4 anchor points of the 7 points. Each item had a brief description of the judgement to be made and a set of suggested probes for the clinician. The total score was calculated as the sum of all 21 items giving a range of 0 to 126, where the higher score indicated normal or unimpaired functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: units on a scale				
least squares mean (confidence interval 95%)	2.08 (-0.8 to 4.97)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in the 'Common Objects and Activities' QLS Domain Score

End point title	Change From Baseline to Week 12 in the 'Common Objects and Activities' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Common Objects and Activities domain score was calculated as the sum of 2 items (numbers 18 and 19) giving a range of 0 to 12, where the higher score indicated less unimpaired functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: units on a scale				
arithmetic mean (standard deviation)	0.1 (± 1.16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in the 'Intrapsychic Foundations' QLS Domain Score

End point title	Change From Baseline to Week 12 in the 'Intrapsychic Foundations' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Intrapsychic Foundations domain score was calculated as the sum of 7 items (numbers 13 to 17 and 20 and 21) giving a range of 0 to 42, where the higher score indicated less unimpaired functioning

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: units on a scale				
arithmetic mean (standard error)	0.73 (± 4.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in the 'Interpersonal Relations' QLS Domain Score

End point title	Change From Baseline to Week 12 in the 'Interpersonal Relations' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Interpersonal Relations domain score was calculated as the sum of 8 items (numbers 1 to 8) giving a range of 0 to 48, where the higher score indicated less unimpaired functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: units on a scale				
arithmetic mean (standard deviation)	0.67 (± 4.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in the 'Instrumental Role' QLS Domain Score

End point title	Change From Baseline to Week 12 in the 'Instrumental Role' QLS Domain Score

End point description:

The QLS is a clinician-rated scale designed to assess deficit symptoms of schizophrenia and functioning during the preceding 4 weeks. The QLS consists of 21 items in 4 domains: Interpersonal Relations (eight items), Instrumental Role (four items), Intrapsychic Foundations (seven items), and Common Objects and Activities (two items). Each item was rated on a 7-point scale, from 0 (severe impairment) to 6 (normal or unimpaired functioning). The Instrumental Role domain score was calculated as the sum of 4 items (numbers 9 to 12) giving a range of 0 to 24, where the higher score indicated less unimpaired

functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: units on a scale				
arithmetic mean (standard deviation)	0.02 (± 2.53)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 28 in the TooL Total Score

End point title	Change From Baseline to Week 28 in the TooL Total Score

End point description:

Tolerability and Quality of Life (TooL) is a patient-rated scale developed to measure the impact of side-effects on the quality of life in patients treated with antipsychotic medication. The TooL consists of 8 domains: mood (worry-upset), function capabilities, fatigue-weakness, weight gain, stiffness-tremor, physical restlessness, sexual dysfunction, and dizziness-nausea. Each domain was rated on a four-point scale from 1 (no impact) to 4 (maximum impact). Total scores ranged from 8 (no impact) to 32 (maximum impact).

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.16 (-0.85 to 0.53)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in ASEX Total Score

End point title	Change From Baseline to Week 12 in ASEX Total Score

End point description:

The Arizona Sexual Experience Scale (ASEX) is a five-item, patient-rated scale that evaluates a patient's recent sexual experiences. The ASEX is used to identify individuals with sexual dysfunction. Patients were asked to assess their own experiences over the last week (for example, "How strong is your sex drive?", "Are your orgasms satisfying?") and respond on a six-point scale for each item. Possible total scores range from 5 to 30. Higher ASEX total scores indicate more sexual dysfunction (hypofunction).

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.74 (-2.03 to 0.56)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in the WoRQ Total Score

End point title	Change From Baseline to Week 12 in the WoRQ Total Score

End point description:

The Readiness for Work Questionnaire (WoRQ) is a clinician-rated scale designed to measure a schizophrenic patient's ability to work. The WoRQ consists of 8 items: the clinician had to rate 7 statements and answer 1 question. The statements were rated on a four-point scale, from 'strongly agree', 'agree', 'disagree' or 'strongly disagree' based on all material available (for example, personal notes, medical records, input from other health professionals, family members or caregivers); and in the final item, the clinician had to indicate if the patient was ready for work or not (by indicating either 'yes' or 'no'). Lower WoRQ total scores indicate better functioning.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.55 (-1.2 to 0.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Patients Categorised As Sexually Dysfunctional Measured at Week 24 on the ASEX Scale

End point title	Patients Categorised As Sexually Dysfunctional Measured at Week 24 on the ASEX Scale

End point description:

The Arizona Sexual Experience Scale (ASEX) is a five-item, patient-rated scale that evaluates a patient's recent sexual experiences. The ASEX is used to identify individuals with sexual dysfunction. Patients were asked to assess their own experiences over the last week (for example, "How strong is your sex drive?", "Are your orgasms satisfying?") and respond on a six-point scale for each item. Possible total scores range from 5 to 30. Higher ASEX total scores indicate more sexual dysfunction (hypofunction). The presence of sexual dysfunction based on the ASEX scale was defined as an ASEX total score of ≥19, or a score of ≥5 on any item, or a score of ≥4 on any 3 items

End point type	Secondary

End point timeframe:

Week 24

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: Number of participants	31			

Statistical analyses

No statistical analyses for this end point

Secondary: Patients Categorised As Sexually Dysfunctional Measured at Week 12 on the ASEX Scale

End point title	Patients Categorised As Sexually Dysfunctional Measured at Week 12 on the ASEX Scale

End point description:

The Arizona Sexual Experience Scale (ASEX) is a five-item, patient-rated scale that evaluates a patient's recent sexual experiences. The ASEX is used to identify individuals with sexual dysfunction. Patients were asked to assess their own experiences over the last week (for example, "How strong is your sex drive?", "Are your orgasms satisfying?") and respond on a six-point scale for each item. Possible total scores range from 5 to 30. Higher ASEX total scores indicate more sexual dysfunction (hypofunction). The presence of sexual dysfunction based on the ASEX scale was defined as an ASEX total score of ≥19, or a score of ≥5 on any item, or a score of ≥4 on any 3 items.

End point type	Secondary

End point timeframe:

week 12

End point values	Aripiprazole			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: participants	32			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
First dose to follow-up	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups	
Reporting group title	Aripiprazole Once-monthly
Reporting group description:	
Aripiprazole once-monthly: 400 or 300 mg/month; 6 intramuscular (IM) injections starting at baseline	

Serious adverse events	Aripiprazole Once-monthly		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 88 (3.41%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Alcoholism			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysphoria			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Aripiprazole Once-monthly		
Total subjects affected by non-serious adverse events subjects affected / exposed	6 / 88 (6.82%)		
Investigations Weight increased subjects affected / exposed	6 / 88 (6.82%)		
occurrences (all)	6		

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

None reported