EudraCT Results Form

Trial Information

A. Trial Identification

Full title of the trial

Patient and Physician Preferences and Satisfaction with Oral and Long-acting Injectable Long-term Antipsychotic Treatment for Psychotic Disorders

EudraCT Number	2009-011343-39
Sponsor Protocol Code	RIS-SCH-4226
ISRCTN Number	
ClinicalTrials.gov identifier (NCT Number)	
WHO Universal Trial Reference Number (UTRN)	

Other trial identifiers

Other identifier name	Other identifier code

B. Paediatric Regulatory Details

Is the trial part of an agreed Paediatric Investigation Plan (PIP)?	No
Paediatric Investigation Plan(s)	EMA Decision number of Paediatric Investigation Plan(s)
Enter the EMA paediatric Investigation plan number(s) (PIP) using the following format: EMEA-999999-PIP99-99, where 9 is a number (0-9 inclusive).	
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

C. Sponsor Details

Name	Scientific Contact	Public Contact
Organisation name: Janssen-Cilag AB	**Functional contact name:** Clinical Registry Group	**Functional contact name:** Clinical Registry Group
Street Address: Kolonnvägen 45	**Organisation name:** Janssen-Cilag AB	**Organisation name:** Janssen-Cilag AB
Town/City: 170 67 Solna	**Country code:**	**Country code:**
Country: Sweden	**Phone Number:**	**Phone Number:**
Post code:	**Email address:** ClinicalTrialsEU@its.jnj.com	**Email address:** ClinicalTrialsEU@its.jnj.com

D. Results Analysis Stage

Analysis Stage	Final
Date of interim/Final Analysis	2010-11-02
Is this the analysis of the primary completion data?	No
Primary completion date	
Global end of trial date reached?	Yes
Global end of trial date	2010-11-02
Was the trial ended prematurely?	No

E. General Information About Trial

Main objective of Trial

The main objective of the study was to compare overall patient treatment satisfaction with current medication in patients with schizophrenia, schizoaffective disorder, delusional disorder, psychotic disorder NOS (not otherwise specified) or any other psychotic disorder. Three treatment groups were included: 1) Atypical oral antipsychotics; 2) Conventional long acting injections (LAI) antipsychotics; 3) Atypical LAI antipsychotic (Risperdal Consta®).

The actual start date of recruitment must be the current date or a date in the past.

Actual Start date of Recruitment 2009-09-08

Long term follow up planned? No

Long term follow up rationale

Long term follow up duration

Independent data monitoring committee (IDMC) involvement? No

Protection of trial subjects

Patients were informed about documentation of their treatment data within a non-interventional study. Prior to inclusion in this study, it was required that all patients signed the informed consent allowing source data verification in accordance with the data protection law.

Background therapy

Evidence of comparator(s)

F. Population of Trial Subjects

Subject number per country

Country	Actual number of subjects enrolled
Sweden	106
Norway	52
Finland	66
Denmark	40
Total: worldwide	264
Total: EEA	264

Age group breakdown for Trial

Age Range	Actual number of subjects enrolled
In Utero	0
Pre-term 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)	264
From 65 years	
Elderly (From 65-84 years)	0
Elderly 85 years and over	0
Total	264

Subject Disposition

Subject Disposition

Recruitment Details

Pre-Assignment

Screening Details

264 subjects in the Nordic countries were included and were assessed for preference and satisfaction for different forms of administration of antipsychotic treatments.

Pre-Assignment Period

Periods

Overall Study

(overall period)

Blinding Implementation Details:

Is this the baseline period? true

Mutually exclusive arms? true

Non-Mutual Exclusive Number of Subjects:

Allocation: Non-Randomised-Controlled

Blinding Used: Not-blind

Roles Blinded:

Started

Atypical Oral Antipsychotics (Other) Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	Conventional LAI Antipsychotics (Other) Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	Atypical LAI Antipsychotic (Risperdal Consta®) (Other) Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	Total *(=sum per row)*
144	57	63	264 *(calculated)*

Completed

Atypical Oral Antipsychotics (Other) Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	Conventional LAI Antipsychotics (Other) Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	Atypical LAI Antipsychotic (Risperdal Consta®) (Other) Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study.	Total *(=sum per row)*

		Subjects did not receive any drug as a part of this study.	
144	57	63	264 *(calculated)*

Reasons Not Completed

Reasons Joined

Products

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration
Atypical Oral Antipsychotics	Atypical Oral Antipsychotics			There was no study medication in this study. Patients were using antipsychotic medication, which was prescribed by patient's treating physician.	Tablet, Capsule, Oral solution	Oral use
Conventional LAI Antipsychotics	Conventional LAI Antipsychotics			There was no study medication in this study. Patients were using antipsychotic medication, which was prescribed by patient's treating physician.	Injection	Intramuscular use
Atypical LAI Antipsychotic (Risperdal Consta®)	Risperdal Consta			There was no study medication in this study. Patients were using antipsychotic medication, which was prescribed by patient's treating physician.	Injection	Intramuscular use

Baseline Characteristics

Baseline Characteristics Information

The baseline Period is : Overall Study

How are baseline characteristics being reported?

Per Arm in the baseline period

Subject Analysis Sets

Reporting Groups

Reporting Group Title	Number of subjects	Description	Options
Atypical Oral Antipsychotics	144	Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	
Conventional LAI Antipsychotics	57	Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	
Atypical LAI Antipsychotic (Risperdal Consta®)	63	Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	

Age Characteristics

Title: Age Categorical

Description:

Unit: Subjects

Reporting Group Values	Atypical Oral Antipsychotics	Conventional LAI Antipsychotics	Atypical LAI Antipsychotic (Risperdal Consta®)	Total
Overall number of baseline subjects	144	57	63	264 (calculated)
In utero	0	0	0	0

Reporting Group Values	Atypical Oral Antipsychotics	Conventional LAI Antipsychotics	Atypical LAI Antipsychotic (Risperdal Consta®)	Total
Preterm newborn infants (gestational age < 37 wks)	0	0	0	0
Newborns (0-27 days)	0	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0	0
Children (2-11 years)	0	0	0	0
Adolescents (12-17 years)	0	0	0	0
Adults (18-64 years)	144	57	63	264
From 65-84 years	0	0	0	0
85 years and over	0	0	0	0
Total	144 (calculated)	57 (calculated)	63 (calculated)	264 (calculated)

Title: Age Continuous

Description:

Unit: years

Central Tendency Type: Arithmetic Mean

Dispersion Type: Standard Deviation

Reporting Group Values	Atypical Oral Antipsychotics		Conventional LAI Antipsychotics		Atypical LAI Antipsychotic (Risperdal Consta®)	
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Unit of measure (years)	38.4	12.85	46.8	9.92	44.8	15.07

Gender Characteristics

Title: Gender Categorical

Description:

Unit: Subjects

Reporting Group Values	Atypical Oral Antipsychotics	Conventional LAI Antipsychotics	Atypical LAI Antipsychotic (Risperdal Consta®)	Total
Overall number of baseline subjects	144	57	63	264
Female	70	30	27	127
Male	74	27	36	137

Study Categorical Characteristics

Study Continuous Characteristics

End Points

Reporting Groups

Periods	Arms
Overall Study (overall period)	Atypical Oral Antipsychotics
	Conventional LAI Antipsychotics
	Atypical LAI Antipsychotic (Risperdal Consta®)

End Points

Primary: Medication Satisfaction Questionnaire (MSQ) Score

Countable or measurable? Measurable

Description: Patient satisfaction with the study medication was assessed using the Medication Satisfaction Questionnaire (MSQ) a 1-item global patient-rated scale. Specifically, patients were asked to respond on a 7-point scale, ranging from extremely dissatisfied (1) to extremely satisfied (7), to the following: "The way you feel about taking your study medication is". This endpoint was analyzed on all enrolled subjects in this study.

Time Frame: At a single point in time for each subject (up to 1 year and 1 month)

Measure Type: Arithmetic Mean

Precision/Dispersion Type: Standard Deviation

Units: Score on a scale

Percentage:

Arm Reporting Groups						
	Overall Study Atypical Oral Antipsychotics		**Overall Study Conventional LAI Antipsychotics**		**Overall Study Atypical LAI Antipsychotic (Risperdal Consta®)**	
Number of subjects that started the Arm:	144		57		63	
Number of Subjects Analyzed:	144		57		63	
Comment: (The comment is mandatory when the number of subjects analysed is zero)						
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
MSQ (patient)	5.2	1.3	4.4	1.6	5.0	1.5
MSQ (physician)	4.9	1.4	4.6	1.3	4.8	1.4

Statistical Analysis	
Reporting Groups	
Overall Study Arm: Atypical Oral Antipsychotics	
Arm: Atypical LAI Antipsychotic (Risperdal Consta®)	
Subject Analysis Groups	
Nothing selected	
Statistical Analysis Details	
Analysis Title	Statistical Analysis 1 (MSQ- Patient)
Analysis Description	

Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	Non-Inferiority
Subjects in this analysis	207
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.2348
P-Value Comment	
Method	ANOVA
Parameter Estimate	
Parameter Type	
Point Estimate	
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-0.6497
Upper Limit	0.1602
Variability Estimate	
Dispersion Value	

Statistical Analysis

Reporting Groups

Overall Study
Arm: Atypical Oral Antipsychotics

Arm: Atypical LAI Antipsychotic (Risperdal Consta®)

Subject Analysis Groups

Nothing selected

Statistical Analysis Details

Analysis Title	Statistical Analysis 2 (MSQ- Physician)

Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	Non-Inferiority
Subjects in this analysis	207
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.6733
P-Value Comment	
Method	ANOVA
Parameter Estimate	
Parameter Type	
Point Estimate	
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-0.5020
Upper Limit	0.3249
Variability Estimate	
Dispersion Value	

Statistical Analysis

Reporting Groups

Overall Study
Arm: Atypical Oral Antipsychotics

Arm: Conventional LAI Antipsychotics

Subject Analysis Groups

Nothing selected

Statistical Analysis Details

Analysis Title	Statistical Analysis 3 (MSQ- Patient)
Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	Non-Inferiority
Subjects in this analysis	201
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.0002
P-Value Comment	
Method	ANOVA
Parameter Estimate	
Parameter Type	
Point Estimate	
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	0.3802
Upper Limit	1.2321
Variability Estimate	
Dispersion Value	

Statistical Analysis

Reporting Groups

Overall Study
Arm: Atypical Oral Antipsychotics

Arm: Conventional LAI Antipsychotics

Subject Analysis Groups

Nothing selected

Statistical Analysis Details	
Analysis Title	Statistical Analysis 4 (MSQ- Physician)
Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	Non-Inferiority
Subjects in this analysis	201
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.3318
P-Value Comment	
Method	ANOVA
Parameter Estimate	
Parameter Type	
Point Estimate	
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-0.2105
Upper Limit	0.6206
Variability Estimate	
Dispersion Value	

Statistical Analysis
Reporting Groups
Arm: Conventional LAI Antipsychotics
Arm: Atypical LAI Antipsychotic (Risperdal Consta®)
Subject Analysis Groups

Nothing selected	
Statistical Analysis Details	
Analysis Title	Statistical Analysis 5 (MSQ- Patient)
Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	Non-Inferiority
Subjects in this analysis	120
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.0475
P-Value Comment	
Method	ANOVA
Parameter Estimate	
Parameter Type	
Point Estimate	
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	0.0062
Upper Limit	1.1166
Variability Estimate	
Dispersion Value	

Statistical Analysis
Reporting Groups
Arm: Conventional LAI Antipsychotics
Arm: Atypical LAI Antipsychotic (Risperdal Consta®)

Subject Analysis Groups	
Nothing selected	
Statistical Analysis Details	
Analysis Title	Statistical Analysis 6 (MSQ- Physician)
Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	Non-Inferiority
Subjects in this analysis	120
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.6377
P-Value Comment	
Method	ANOVA
Parameter Estimate	
Parameter Type	
Point Estimate	
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-0.3721
Upper Limit	0.6051
Variability Estimate	
Dispersion Value	

Secondary: Clinical Global Impression – Severity Score

Countable or measurable? Measurable

Description: The CGI scale for Severity of Illness is a standardized assessment tool to rate the overall severity of illness and efficacy of medication. Scores on the CGI-S range from 1 (not ill at all) to 7 (among the most extremely ill). This endpoint was analyzed on all enrolled subjects in this study.

Time Frame: At a single point in time for each subject (up to 1 year and 1 month)

Measure Type: Arithmetic Mean

Precision/Dispersion Type: Standard Deviation

Units: Score on a scale

Percentage:

Arm Reporting Groups						
	Overall Study Atypical Oral Antipsychotics		**Overall Study Conventional LAI Antipsychotics**		**Overall Study Atypical LAI Antipsychotic (Risperdal Consta®)**	
Number of subjects that started the Arm:	144		57		63	
Number of Subjects Analyzed:	144		57		63	
Comment: (The comment is mandatory when the number of subjects analysed is zero)						
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
	3.7	1.05	3.9	1.26	3.8	1.15

Adverse Events

Adverse Events

Adverse Events Information

Timeframe for adverse event reporting Not Applicable

Adverse events reporting additional description

Assessment Type Non Systematic

Frequency threshold for reporting non-serious adverse events: 0

Dictionary name Other

Dictionary name - if other	Not Applicable
Dictionary version	0.0

Adverse Events Reporting Groups

Reporting Group Totals	**Atypical Oral Antipsychotics** Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	**Conventional LAI Antipsychotics** Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.	**Atypical LAI Antipsychotic (Risperdal Consta®)** Subjects treated with their current main antipsychotic treatment for a minimum of 6 and a maximum of 24 months and stable on their current medication (i.e., the subjects have according to clinical judgment, been stable during the past three months without a need for major interventions due to clinical deterioration [like hospitalization and/or major changes in medication]) were included in the study. Subjects did not receive any drug as a part of this study.
Total # Subjects Exposed	144	57	63
Total # Subjects Affected by Serious Adverse Events	0	0	0
Total # Subjects Affected by Non Serious Adverse Events	0	0	0
Total # of Deaths (all causes)	0	0	0
Total # of Deaths Resulting From Adverse Events			

Serious Adverse Events

Reporting Groups	**Atypical Oral Antipsychotics**	**Conventional LAI Antipsychotics**	**Atypical LAI Antipsychotic (Risperdal Consta®)**

Non Serious Adverse Events

Threshold for non-serious adverse event reporting is: 0%

Reporting Groups	**Atypical Oral Antipsychotics**	**Conventional LAI Antipsychotics**	**Atypical LAI Antipsychotic (Risperdal Consta®)**

More Information

More Information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Amendment Date	Description

Interruptions (globally)

For any interruption, the restart date must not be before the interruption date.

Were there any global interruptions to the trial? No

Interruption Date	Description	Restart Date

Limitations and caveats

Limitations and caveats applicable to this summary of the results This is an Observational (Non-Interventional) study. Therefore, Adverse events were not collected in this study.

Online References

Provide identifiers to retrieve publications of interest in regards to the results of this clinical trial. **Enter PubMed Identifier (PMID)**