ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 10/02/2012

ClinicalTrials.gov ID: NCT00600756

Study Identification

Unique Protocol ID:	D1443L00039
Brief Title:	Comparison of the Subjective Well-being and Tolerability of Quetiapine XR to Risperidone (RECOVER)
Official Title:	A One-Year Randomized, Prospective, Parallel, Open Comparison of Subjective Well-being in Schizophrenic Out-patients Treated With Quetiapine XR (SEROQUEL XR™) or Oral Risperidone at Flexible Dose in a Naturalistic Setting
Secondary IDs:	

Study Status

Record Verification:	October 2012
Overall Status:	Completed
Study Start:	January 2008
Primary Completion:	October 2009 [Actual]
Study Completion:	October 2009 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 12APR08 Board Name: De Videnskabsetiske Komiteer for Region Hovedstaden Board Affiliation: De Videnskabsetiske Komiteer for Region Hovedstaden Phone: 48 20 50 00 Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment Brazil: Ministry of Health Bulgaria: Ministry of Health Costa Rica: Ministry of Health Costa Rica Denmark: Ministry of Health Finland: Ministry of Social Affairs and Health Germany: Federal Institute for Drugs and Medical Devices Italy: National Institute of Health Mexico: National Institute of Public Health, Health Secretariat Portugal: National Pharmacy and Medicines Institute Romania: Ministry of Public Health Russia: Ministry of Health of the Russian Federation Spain: Ministry of Health and Consumption Switzerland: Federal Office of Public Health Turkey: Ministry of Health

Study Description

Brief Summary:	The trial is designed to assess the long term subjective well-being in schizophrenic outpatients treated with quetiapine XR (extended release) or oral risperidone at flexible dose in a naturalistic setting over a period of one year. Secondary outcome measures have been selected for helping in the differentiation of the compared atypical antipsychotics. The primary objective of this study is to demonstrate the non-inferiority of quetiapine XR to risperidone assessed at month 6 in terms of responder rate using the self-report instrument SWN-K
Detailed Description:	

Conditions

Conditions:	Schizophrenic Disorders
Keywords:	schizophrenia

SWNK

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	798 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Quetiapine XR	Drug: Quetiapine XR Oral, once daily, tablets of 400 mg to 800 mg Other Names: • Seroquel XR
Active Comparator: Risperidone	Drug: Risperidone Oral, once daily, tablets of 2 mg to 6 mg Other Names: • Risperdal

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	65 Years
Gender:	Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Treated for symptomatic schizophrenia (DSM-IV-TR codes: 295.10, 295.20, 295.30,295.60, 295.90) or schizoaffective disorder (DSM-IV-TR code:295.70) or schizophreniform disorder (DSM-IV-TR code: 295.40). Patients with co-morbid depressive symptoms may be enrolled
- Patient with first episode of the above mentioned disease (item 3) or patient requiring a medication change for clinical reasons (effectiveness, tolerability, compliance, patient preference), i.e. switch from typical to atypical neuroleptics, switch from other atypical neuroleptics, excluding patients treated with risperidone or quetiapine at the time of enrolment.

Exclusion Criteria:

- Patients with a baseline SWN-K total score of >75
- Patients with previous treatment with risperidone or quetiapine may be enrolled if change of treatment has not been dictated by major lack of tolerability and efficacy and if date of last dose has been at least 3 months prior to enrolment.

Contacts/Locations

Study Officials: Martin Brecher, MSD
Study Director
AstraZeneca

Prof Naber, MD
Study Principal Investigator
Klinikum Eppendorf

Locations: Belgium
Research Site
Assebroek, Belgium, Belgium

Research Site
Hasselt, Belgium, Belgium

Research Site
Liege, Belgium, Belgium

Research Site
Montignies-sur-sambre, Belgium, Belgium

Research Site
Roeselare, Belgium, Belgium

Research Site
Sint-denijs-westrem, Belgium

Research Site
Tournai, Belgium

Brazil
Research Site
Aparecida de Goiania, GO, Brazil

Research Site
Belo Horizonte, Minas Gerais, Brazil

Research Site
Botucatu, Brazil

Research Site
Curitiba, PR, Brazil

Research Site
Fortaleza, CE, Brazil

Research Site
Itapira, SP, Brazil

Research Site
Porto Alegre, RS, Brazil

Research Site
Recife, PE, Brazil

Research Site
Ribeirao Preto, SP, Brazil

Research Site
Rio de Janeiro, Rio de Janeiro, Brazil

Research Site
Salvador, BA, Brazil

Research Site
Sao Paulo, SP, Brazil

Research Site
Sorocaba, SP, Brazil

Bulgaria
Research Site
Cerova Koria Village, Veliko Tarnovo, Bulgaria

Research Site
Pazardjik, Bulgaria

Research Site
Pleven, Bulgaria

Research Site
Plovdiv, Bulgaria

Research Site
Sofia, Bulgaria

Research Site
Stara Zagora, Bulgaria

Research Site
Varna, Bulgaria

Costa Rica
Research Site
Barrio Los Yoses, San Jose, Costa Rica

Research Site
Curridabat, San Jose, Costa Rica

Research Site
Guadalupe, San Jose, Costa Rica

Finland
Research Site
Helsinki, Finland

Research Site
Kitee, Finland

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Kuopio, Finland

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Lapua, Finland

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Pori, Finland

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Raahe, Finland

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Rovaniemi, Finland

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Tampere, Finland

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Turku, Finland

Germany
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Bad Saarow, Germany

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Berlin, Germany

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Bielefeld, Germany

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Bochum, Germany

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Butzbach, Germany

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Darmstadt, Germany

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Duisburg, Germany

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Gelsenkirchen, Germany

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Grevenbroich, Germany

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Hamburg, Germany

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Hattingen, Germany

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Hildesheim, Germany

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Koln, Germany

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Konigsbruck, Germany

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Mittweida, Germany

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Munchen, Germany

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Oranienburg, Germany

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Siegen, Germany

Research Site
Stralsund, Germany

Research Site
Wismar, Germany

Italy
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Ancona, Italy

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Andria, BA, Italy

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Chioggia, VE, Italy

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Feltre, BL, Italy

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Fidenza, PR, Italy

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Genova, GE, Italy

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Maddaloni, CE, Italy

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Milano, MI, Italy

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Palmi, RC, Italy

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Parma, PR, Italy

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Perugia, PG, Italy

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Pompei, Italy

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Rimini, RN, Italy

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Salerno, SA, Italy

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Sassari, SS, Italy

Research Site
Sora, FR, Italy

Mexico
Research Site
Guadalajara Jalisco, Mexico

Research Site
Mexico, D.F, Mexico

Research Site
Mexico, D.f., Mexico

Research Site
Mexico, Mexico

Research Site
Monterrey, Nuevo Leon, Mexico, Mexico

Research Site
SLP, SLP, Mexico

Research Site
Yucatan, Mexico

Portugal
Research Site
Abraveses, Portugal

Research Site
Braga, Portugal

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Coimbra, Portugal

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Lisboa, Portugal

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Porto, Portugal

Research Site
Santarem, Portugal

Romania
Research Site
Bucharest, Romania

Research Site
Craiova, Romania

Research Site
Galati, Galati, Romania

Research Site
Pitesti, Arges, Romania

Research Site
Sibiu, Romania

Russian Federation
Research Site
Kazan, Russian Federation

Research Site
Moscow, Russia, Russian Federation

Research Site

Moscow, Russian Federation

Research Site
St. Petersburg, Russian Federation

Spain
Research Site
Elche (alicante), Comunidad Valenciana, Spain

Research Site
Jaen, Andalucia, Spain

Research Site
Madrid, Comunidad de Madrid, Spain

Research Site
Malaga, Andalucia, Spain

Research Site
Mataro (barcelona), Cataluna, Spain

Research Site
Salamanca, Castilla Leon, Spain

Research Site
Sama de Langreo, Asturias, Spain

Research Site
San Juan de Alicante, Comunidad Valenciana, Spain

Research Site
Sevilla, Andalucia, Spain

Research Site
Vigo, Galicia, Spain

Research Site
Zamora, Castilla Leon, Spain

Research Site
Zamudio (vizcaya), Pais Vasco, Spain

Switzerland
Research Site
Prilly, Waadt, Switzerland

Research Site
WIL, Switzerland

Turkey
Research Site
Ankara, Turkey

Research Site
Elazig, Turkey

Research Site
Istanbul, Turkey, Turkey

Research Site
Izmir, Turkey

Research Site
Manisa, Turkey, Turkey

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	This study was a 1-year, randomized, prospective, parallel, open-label study. The study was conducted in 114 study centers in 13 countries. OR International multi-center study, 180 sites recruited between January 2008 and October 2009.
Pre-Assignment Details	Screening for eligibility. Patients with a SWN-K total score ≤ 75 were entered into the study. All patients with “no intake of IP and missing SWN-K total score at baseline or following baseline were included in the study “Overall Number of Participants” but these patients are excluded from the ITT Analysis set!

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator – oral, once daily, tablets of 2 mg to 6 mg

Analysis After 6 Months

	Quetiapine XR	Risperidone
Started	395	403
Completed	264 [1]	283 [1]
Not Completed	131	120
Adverse Event	43	33
Withdrawal by Subject	38	30
Incorrect Enrollment	12	21
worsening symptom, lack of efficacy	11	14
Severe non-compliance to protocol	11	11
Lost to Follow-up	10	8
Study-specific discontinuation criteria	6	3

[1] Completers are all patients who completed the study up to Visit 5 (including premature withdraw)

Overall Study Analysis After 12 Months

	Quetiapine XR	Risperidone
Started	395	403
Randomized Analysis	395	403
Safety Analysis	391	402
ITT Analysis	379	392
Completed	212 [1]	227 [1]
Not Completed	183	176
Adverse Event	53	44
Withdrawal by Subject	51	41

	Quetiapine XR	Risperidone
Incorrect enrollment	21	29
worsening symptom, lack of efficacy	17	20
Severe non-compliance to protocol	16	20
Lost to Follow-up	16	13
Study-specific discontinuation criteria	9	9

[1] Completed study to Visit 7 (includes premature withdrawals with final visit in the Visit 7 window)

Baseline Characteristics

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator – oral, once daily, tablets of 2 mg to 6 mg

Baseline Measures

	Quetiapine XR	Risperidone	Total
Number of Participants	395	403	798
Age, Continuous [units: Years] Mean (Standard Deviation)	39.3 (11.7)	40.0 (11.66)	39.7 (11.67)
Gender, Male/Female [units: Participants]			
Female	162	171	333
Male	233	232	465

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Responder Rate at Month 6 in the Per Protocol Population Using the Subjective Well-being Under Neuroleptics Scale, Short Version (SWN-K) Total Score

Measure Description	The SWN-K is comprised of 20 questions, rated on a 6-point scale from 1 (not at all) to 6 (very much). Scores range from 20 to 120, with higher scores implying higher subjective well-being. A responder is defined as a subject with an increase of 10 points or 20% from baseline in SWN-K total score (non-inferiority limit of -9.7% in responder rate)
Time Frame	6 months
Safety Issue?	No

Analysis Population Description

For Per Protocol at Month 6 analysis, the difference from Randomized analysis (395) was no study drug (4); SWN-K score missing (12), and did not meet inclusion criteria (169) for Quetiapine XR. For Risperidone, the difference from Randomized analysis (403) was no study drug (1); SWN-K score missing (10), and did not meet inclusion criteria (160).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	210	232
Responder Rate at Month 6 in the Per Protocol Population Using the Subjective Well-being Under Neuroleptics Scale, Short Version (SWN-K) Total Score [units: Participants]	136	158

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Mean Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Total Score at Month 12 in the Per Protocol Population
Measure Description	The SWN-K is comprised of 20 questions, each of which is rated using a 6-point scale ranging from 1 (not at all) to 6 (very much). Possible scores range from 20 to 120, with higher scores implying higher subjective well-being.
Time Frame	Baseline and Month 12
Safety Issue?	No

Analysis Population Description

For Per Protocol at Month 12 analysis, the difference from Randomized analysis (395) was no study drug (4); SWN-K score missing (12), and did not meet inclusion criteria (206) for Quetiapine XR. For Risperidone, the difference from Randomized analysis (403) was no study drug (1); SWN-K score missing (10), and did not meet inclusion criteria (201).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	173	191
Change From Baseline in Mean Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Total Score at Month 12 in the Per Protocol Population [units: Scores on a scale] Least Squares Mean (Standard Error)	23.2 (1.55)	21.1 (1.49)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Mean Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Total Score at Month 12 in the Intent-to-Treat (ITT) Population
Measure Description	The SWN-K is comprised of 20 questions, each of which is rated using a 6-point scale ranging from 1 (not at all) to 6 (very much). Possible scores range from 20 to 120, with higher scores implying higher subjective well-being.
Time Frame	Baseline and Month 12
Safety Issue?	No

Analysis Population Description

For Per Protocol at Month 12 analysis, the difference from Randomized analysis (395) was no study drug (4); SWN-K score missing (12), and did not meet inclusion criteria (206) for Quetiapine XR. For Risperidone, the difference from Randomized analysis (403) was no study drug (1); SWN-K score missing (10), and did not meet inclusion criteria (201).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg

	Description
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
Change From Baseline in Mean Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Total Score at Month 12 in the Intent-to-Treat (ITT) Population [units: Scores on a scale] Least Squares Mean (Standard Error)	22.7 (1.34)	19.4 (1.0)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Physical Functioning at Month 12 in the ITT Population.
Measure Description	The SWN-K total score is the sum of 5 subscores (4 questions each): physical functioning, social integration, mental functioning, self-control, and emotional regulation. The subscores are rated using a 6-point scale (the higher the grade, the better the response). Possible subscores range from 4 to 24.
Time Frame	Baseline and 12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392

	Quetiapine XR	Risperidone
Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Physical Functioning at Month 12 in the ITT Population. [units: Scores on a scale] Least Squares Mean (Standard Error)	4.9 (0.32)	4.0 (0.31)

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Social Integration at Month 12 in the ITT Population.
Measure Description	The SWN-K total score is the sum of 5 subscores (4 questions each): physical functioning, social integration, mental functioning, self-control, and emotional regulation. The subscores are rated using a 6-point scale (the higher the grade, the better the response). Possible subscores range from 4 to 24.
Time Frame	Baseline and 12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Social Integration at Month 12 in the ITT Population. [units: Scores on a scale] Least Squares Mean (Standard Error)	4.6 (0.32)	4.0 (0.31)

6. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Mental Functioning at Month 12 in the ITT Population.
Measure Description	The SWN-K total score is the sum of 5 subscores (4 questions each): physical functioning, social integration, mental functioning, self-control, and emotional regulation. The subscores are rated using a 6-point scale (the higher the grade, the better the response). Possible subscores range from 4 to 24.
Time Frame	Baseline and 12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Mental Functioning at Month 12 in the ITT Population. [units: Scores on a scale] Least Squares Mean (Standard Error)	4.9 (0.31)	3.9 (0.30)

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Self-control at Month 12 in the ITT Population.

Measure Description	The SWN-K total score is the sum of 5 subscores (4 questions each): physical functioning, social integration, mental functioning, self-control, and emotional regulation. The subscores are rated using a 6-point scale (the higher the grade, the better the response). Possible subscores range from 4 to 24.
Time Frame	Baseline and 12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Self-control at Month 12 in the ITT Population. [units: Scores on a scale] Least Squares Mean (Standard Error)	4.1 (0.29)	3.8 (0.29)

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Emotional Regulation at Month 12 in the ITT Population.
Measure Description	The SWN-K total score is the sum of 5 subscores (4 questions each): physical functioning, social integration, mental functioning, self-control, and emotional regulation. The subscores are rated using a 6-point scale (the higher the grade, the better the response). Possible subscores range from 4 to 24.
Time Frame	Baseline and 12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
Change From Baseline in the Subjective Well-Being Under Neuroleptic Treatment Scale (SWN-K) Subscale Score: Emotional Regulation at Month 12 in the ITT Population. [units: Scores on a scale] Least Squares Mean (Standard Error)	4.5 (0.32)	3.9 (0.31)

9. Secondary Outcome Measure:

Measure Title	The Remission Rate in Both the Quetiapine XR Group and the Risperidone Group at Month 12 in the ITT Population
Measure Description	Remission was defined as a SWN-K total score greater than or equal to 80. The reported population is participants who showed remission over, time from baseline to Month 12
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	210	227
The Remission Rate in Both the Quetiapine XR Group and the Risperidone Group at Month 12 in the ITT Population [units: Participants]	139	128

10. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population on Core Schizophrenic and Depressive Symptoms by Evaluating the Change From Baseline in CGI-SCH Overall Severity Score (Improved).
Measure Description	For the CGI-SCH overall severity of illness, the score ranged from 1 (normal, not ill) to 7 (among the most severely ill). CGI-SCH score was divided into 3 classes: worsening (change score>0), stable (change score=0) and improved (change score<0). Change from baseline in CGI-SCH overall severity of illness in number of participants with CGI-SCH overall severity score improvement.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	211	227
The Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population on Core Schizophrenic and Depressive Symptoms by Evaluating the Change From Baseline in CGI-SCH Overall Severity Score (Improved).	176	178

	Quetiapine XR	Risperidone
[units: Participants]		

11. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population on Core Schizophrenic and Depressive Symptoms by Evaluating the Change From Baseline in CGI-SCH Overall Severity Score
Measure Description	For the CGI-SCH (Clinical Global Impression-Schizophrenia severity of illness scale) overall severity of illness, the score ranged from 1 (normal, not ill) to 7 (among the most severely ill). Change from baseline in CGI-SCH score was divided into 3 classes: worsening (change score>0), stable (change score=0) and improved (change score<0).
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	211	227
The Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population on Core Schizophrenic and Depressive Symptoms by Evaluating the Change From Baseline in CGI-SCH Overall Severity Score [units: Scores on a scale] Mean (Standard Deviation)	3.8 (0.63)	3.9 (0.67)

12. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population on Core Schizophrenic and Depressive Symptoms by Evaluating the Change From Baseline in the Calgary Depression Scale for Schizophrenia (CDSS) Total Score
Measure Description	The CDSS total score is the sum of 9 questions and ranges from 0 to 27. The higher the score, the more severe are the symptoms.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	351	362
The Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population on Core Schizophrenic and Depressive Symptoms by Evaluating the Change From Baseline in the Calgary Depression Scale for Schizophrenia (CDSS) Total Score [units: Scores on a scale] Least Squares Mean (Standard Error)	-4.7 (0.26)	-3.7 (0.25)

13. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone by Evaluating the Relapse Rate at Month 12 in the ITT Population
Measure Description	Relapse is defined as at least one increase of greater than or equal to 2 points on the CGI-SCH overall severity score during the treatment period or at least one hospitalization due to psychiatric disorders during the treatment period.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The Reported population is participants who showed relapse over time, from baseline to Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
The Effect of Quetiapine XR Versus Risperidone by Evaluating the Relapse Rate at Month 12 in the ITT Population [units: Participants]	43	31

14. Secondary Outcome Measure:

Measure Title	Evaluation of Effect of Quetiapine XR Versus Risperidone on the Health-related Quality of Life of Patients With Schizophrenia by Evaluating the Change From Baseline in EQ-5D(Euro Quality of Life-5 Dimension) Index Score at Month 12 in the ITT Population.
Measure Description	The Euro Quality of Life - 5 dimension index (EQ-5D) is the result of the application of a formula that essentially attaches values (also called weights) to each of the levels (no, some, or heavy problems) in each dimension (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). These weights are issued from a representative sample of the general population. The total possible maximum value was 1 (healthy life) and the minimum value was 0 (death).
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg

	Description
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	343	360
Evaluation of Effect of Quetiapine XR Versus Risperidone on the Health-related Quality of Life of Patients With Schizophrenia by Evaluating the Change From Baseline in EQ-5D(Euro Quality of Life-5 Dimension) Index Score at Month 12 in the ITT Population. [units: Scores on a scale] Least Squares Mean (Standard Error)	0.193 (0.0167)	0.168 (0.0162)

15. Secondary Outcome Measure:

Measure Title	To Evaluate the Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population Regarding Health Economics Outcomes by Evaluating the Functional Improvement Rate of the Modified Vocational Status Index/ Location Code Index: Stable State
Measure Description	Stable State was defined as having the same status in occupational and residential status as at Baseline.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	268	291

	Quetiapine XR	Risperidone
To Evaluate the Effect of Quetiapine XR Versus Risperidone at Month 12 in the ITT Population Regarding Health Economics Outcomes by Evaluating the Functional Improvement Rate of the Modified Vocational Status Index/ Location Code Index: Stable State [units: Participants with stable state]	160	171

16. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Mean Number of Lost School/Work Days at Month 12 in the ITT Population
Measure Description	Workers and students are defined from the modified vocational status index excluding subjects "Retired" or "Unemployed, whether or not expected to work".
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	158	169
The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Mean Number of Lost School/Work Days at Month 12 in the ITT Population [units: Days] Mean (Standard Deviation)	10 (38.54)	6.7 (30.53)

17. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Participants With at Least 1 Hospitalization Due to Psychiatric Disorders at Month 12 in the ITT Population
Measure Description	All hospitalizations due to psychiatric disorders during the study (i.e. from Visit 1 to Termination date + 30 days) in inpatients units, in emergency wards, and in day clinics.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Participants With at Least 1 Hospitalization Due to Psychiatric Disorders at Month 12 in the ITT Population [units: Participants]	37	21

18. Secondary Outcome Measure:

Measure Title	Number of Subjects Who Had an Unscheduled Visits Due to Worsening of Schizophrenia, Dose Change, or Adverse Event at Month 12 in the ITT Population
Measure Description	Unscheduled visits due to worsening of schizophrenia, dose change or adverse event including the hospitalizations due to psychiatric disorders during the study (i.e. from Visit 1 to Termination date + 30 days) in inpatients units, in emergency wards and in day clinics.

Time Frame	Month 12
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
Number of Subjects Who Had an Unscheduled Visits Due to Worsening of Schizophrenia, Dose Change, or Adverse Event at Month 12 in the ITT Population [units: Participants]	94	70

19. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Time Between First Study Drug Intake and First Hospitalization for Patients With 1 Hospitalization in the ITT Population
Measure Description	
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg

	Description
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	35	19
The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Time Between First Study Drug Intake and First Hospitalization for Patients With 1 Hospitalization in the ITT Population [units: Days] Mean (Standard Deviation)	144.3 (97.14)	152.8 (87.86)

20. Secondary Outcome Measure:

Measure Title	Number of Participants Using Antidepressants at Month 12 in the ITT Population
Measure Description	The number of participants who were taking at least 1 antidepressant at Month 12. Antidepressants are all concomitant medications classified in the Anatomical Therapeutic Chemical(ATC)Subgroup "N06-Antidepressants".
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392

	Quetiapine XR	Risperidone
Number of Participants Using Antidepressants at Month 12 in the ITT Population [units: Participants]	72	63

21. Secondary Outcome Measure:

Measure Title	The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Number of Participants Using Other Psychotropic Medications at Month 12 in the ITT Population
Measure Description	Other psychotropic medications include antiepileptics, anti-parkinson drugs, antipsychotics, and antidepressants.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
The Effect of Quetiapine XR Versus Risperidone Regarding Health Economics Outcomes by Evaluating the Number of Participants Using Other Psychotropic Medications at Month 12 in the ITT Population [units: Participants]	138	141

22. Secondary Outcome Measure:

Measure Title	The Compliance of Patients Taking Quetiapine XR Versus Risperidone at Month 12 by Evaluating the Number of Participants Who Returned Study Drug at Month 12 in the ITT Population

Measure Description	
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The ITT analysis set at Month 12 is presented. For Quetiapine XR, there were 168 missing CGI-SCH assessments, resulting in 211 evaluable subjects at Month 12. For Risperidone, there were 165 missing CGI-SCH assessments, resulting in 227 evaluable subjects at Month 12.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	379	392
The Compliance of Patients Taking Quetiapine XR Versus Risperidone at Month 12 by Evaluating the Number of Participants Who Returned Study Drug at Month 12 in the ITT Population [units: Participants]	270	249

23. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants With a Treatment-emergent Adverse Event (TEAEs) at Month 12 in the Safety Population
Measure Description	Treatment-emergent adverse events are defined as adverse events that occurred after the first intake of the study medication (or on the same day).
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The Safety population at Month 12 is presented. For Quetiapine XR, 4 subjects did not take study drug, resulting in 391 evaluable subjects compared with the Randomized population (395 subjects). For Risperidone, 1 subject did not take study drug, results in 402 evaluable subjects compared with the Randomized population (403 subjects).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	391	402
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants With a Treatment-emergent Adverse Event (TEAEs) at Month 12 in the Safety Population [units: Participants]	238	258

24. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants Who Discontinued the Study Because of an TEAE at Month 12 in the Safety Population
Measure Description	Treatment-emergent adverse events are defined as adverse events that occurred after the first intake of the study medication (or on the same day).
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The Safety population at Month 12 is presented. For Quetiapine XR, 4 subjects did not take study drug, resulting in 391 evaluable subjects compared with the Randomized population (395 subjects). For Risperidone, 1 subject did not take study drug, results in 402 evaluable subjects compared with the Randomized population (403 subjects).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	391	402
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants Who Discontinued the Study Because of an TEAE at Month 12 in the Safety Population [units: Participants]	57	48

25. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants Who Had at Least 1 Extra-pyramidal TEAE at Month 12 in the Safety Population
Measure Description	Treatment-emergent adverse events are defined as adverse events that occurred after the first intake of the study medication (or on the same day).
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The Safety population at Month 12 is presented. For Quetiapine XR, 4 subjects did not take study drug, resulting in 391 evaluable subjects compared with the Randomized population (395 subjects). For Risperidone, 1 subject did not take study drug, results in 402 evaluable subjects compared with the Randomized population (403 subjects).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	391	402
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants Who Had at Least 1 Extra-pyramidal TEAE at Month 12 in the Safety Population [units: Participants]	38	83

26. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Extra-pyramidal Events at Month 12 in the Safety Population
Measure Description	Extra-pyramidal events include tremor, hypokinesia, muscle rigidity, hyperkinesia, and extrapyramidal disorder.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The Safety population at Month 12 is presented. For Quetiapine XR, 4 subjects did not take study drug, resulting in 391 evaluable subjects compared with the Randomized population (395 subjects). For Risperidone, 1 subject did not take study drug, results in 402 evaluable subjects compared with the Randomized population (403 subjects).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	391	402
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Extra-pyramidal Events at Month 12 in the Safety Population [units: Events]	51	112

27. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants Who Had at Least 1 Cardiac TEAE at Month 12 in the Safety Population
Measure Description	Treatment-emergent adverse events are defined as adverse events that occurred after the first intake of the study medication (or on the same day).
Time Frame	12 months

Safety Issue?	No

Analysis Population Description

The Safety population at Month 12 is presented. For Quetiapine XR, 4 subjects did not take study drug, resulting in 391 evaluable subjects compared with the Randomized population (395 subjects). For Risperidone, 1 subject did not take study drug, results in 402 evaluable subjects compared with the Randomized population (403 subjects).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	391	402
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants Who Had at Least 1 Cardiac TEAE at Month 12 in the Safety Population [units: Participants]	22	17

28. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Mean Change From Baseline to Month 12 in Prolactin Levels in the Safety Population
Measure Description	The normal range for men is 0 to 14, and for women is 0 to 24.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The Safety population at Month 12 is presented. For Quetiapine XR, 4 subjects did not take study drug, resulting in 391 evaluable subjects compared with the Randomized population (395 subjects). For Risperidone, 1 subject did not take study drug, results in 402 evaluable subjects compared with the Randomized population (403 subjects).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	332	340
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Mean Change From Baseline to Month 12 in Prolactin Levels in the Safety Population [units: ng/mL] Mean (Standard Deviation)	-7.735 (32.8559)	15.990 (46.3367)

29. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR vs Risperidone by Evaluating the Number of Participants at Month 12 in Safety Population With Individual Symptoms Assessed by the Modified Udvalg for Kliniske Undersogelser, Side Effect Rating Scale: Neurologic
Measure Description	Symptoms are graded according to degree (not present to severe) and causal relationship (improbable, possible, probable). An individual AE is defined as an AE with a worse degree compared with Baseline and with a possible or probable relationship to study drug.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

The Safety population at Month 12 is presented. For Quetiapine XR, 4 subjects did not take study drug, resulting in 391 evaluable subjects compared with the Randomized population (395 subjects). For Risperidone, 1 subject did not take study drug, results in 402 evaluable subjects compared with the Randomized population (403 subjects).

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	209	224
The Safety and Tolerability of Quetiapine XR vs Risperidone by Evaluating the Number of Participants at Month 12 in Safety Population With Individual Symptoms Assessed by the Modified Udvalg for Kliniske Undersogelser, Side Effect Rating Scale: Neurologic [units: Participants]	4	20

30. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants at Month 12 in the Safety Population With Individual Symptoms Assessed by the Modified UKU: Hyperprolactinaemia in Women
Measure Description	Symptoms are graded according to degree (not present to severe) and causal relationship (improbable, possible, probable). Hyperprolactinaemia in women is defined as number of women who show the individual adverse event (AE) hyperprolactinaemia. An individual AE Hyperprolactinaemia is defined as an AE with a worse degree of hyperprolactinaemia compared with baseline and with a possible or probable relationship to study drug.
Time Frame	Month 12
Safety Issue?	No

Analysis Population Description

Safety population at Month 12 is presented. Quetiapine XR: Out of 160 evaluable women, 73 were missing individual AE “Hyperprolactinaemia” data.

Risperidone: Out of 171 evaluable women, 74 were missing individual AE “Hyperprolactinaemia” data”.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	87	97

	Quetiapine XR	Risperidone
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants at Month 12 in the Safety Population With Individual Symptoms Assessed by the Modified UKU: Hyperprolactinaemia in Women [units: Participants]	0	10

31. Secondary Outcome Measure:

Measure Title	The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants at Month 12 in the Safety Population With Individual Symptoms Assessed by the Modified UKU: Sexual Dysfunction in Men
Measure Description	Symptoms are graded according to degree (not present to severe) and causal relationship (improbable, possible, probable). Sexual dysfunction in men is defined as number of men who show the individual adverse event (AE) sexual dysfunction. An individual AE sexual dysfunction is defined as an AE with a worse degree of sexual dysfunction compared with baseline and with a possible or probable relationship to study drug.
Time Frame	Month 12
Safety Issue?	No

Analysis Population Description

Safety population at Month 12 is presented. Quetiapine XR: Out of 231 evaluable men, 111 were missing individual AE “Sexual Dysfunction” data”.

Risperidone: Out of 231 evaluable men, 106 were missing individual AE “Sexual Dysfunction” data”.

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator - oral, once daily, tablets of 2 mg to 6 mg

Measured Values

	Quetiapine XR	Risperidone
Number of Participants Analyzed	120	125
The Safety and Tolerability of Quetiapine XR Versus Risperidone by Evaluating the Number of Participants at Month 12 in the Safety Population With Individual Symptoms Assessed by the Modified UKU: Sexual Dysfunction in Men	9	13

	Quetiapine XR	Risperidone
[units: Participants]		

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Quetiapine XR	Experimental - oral, once daily, tablets of 400 mg to 800 mg
Risperidone	Active Comparator – oral, once daily, tablets of 2 mg to 6 mg

Serious Adverse Events

	Quetiapine XR	Risperidone
	Affected/At Risk (%)	Affected/At Risk (%)
Total	45/391 (11.51%)	26/402 (6.47%)
Gastrointestinal disorders		
Constipation [A] †	1/391 (0.26%)	0/402 (0%)
Immune system disorders		
Hypersensitivity [A] †	0/391 (0%)	1/402 (0.25%)
Infections and infestations		
Appendicitis [A] †	1/391 (0.26%)	0/402 (0%)
Injury, poisoning and procedural complications		
Humerus Fracture [A] †	1/391 (0.26%)	0/402 (0%)
Joint Sprain [A] †	1/391 (0.26%)	0/402 (0%)
Investigations		

	Quetiapine XR	Risperidone
	Affected/At Risk (%)	Affected/At Risk (%)
Alanine Aminotransferase Increased [A] †	0/391 (0%)	1/402 (0.25%)
Aspartate Aminotransferase Increased [A] †	0/391 (0%)	1/402 (0.25%)
Osteoarthritis [A] †	1/391 (0.26%)	0/402 (0%)
Metabolism and nutrition disorders		
Anorexia [A] †	0/391 (0%)	1/402 (0.25%)
Diabetes Meelitus [A] †	0/391 (0%)	1/402 (0.25%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bone Neoplasm Malignant [A] †	1/391 (0.26%)	0/402 (0%)
Pituitary Tumor Benign [A] †	0/391 (0%)	1/402 (0.25%)
Nervous system disorders		
Brain Stem Stroke [A] †	0/391 (0%)	1/402 (0.25%)
Epilepsy [A] †	0/391 (0%)	1/402 (0.25%)
Extrapyramidal Disorder [A] †	0/391 (0%)	1/402 (0.25%)
Ischaemic Stroke [A] †	1/391 (0.26%)	0/402 (0%)
Neuroleptic Malignant Syndrome [A] †	0/391 (0%)	1/402 (0.25%)
Psychomotor Hyperactivity [A] †	1/391 (0.26%)	0/402 (0%)
Transient Ischaemic Attack [A] †	0/391 (0%)	1/402 (0.25%)
Psychiatric disorders		
Abnormal Behavior [A] †	2/391 (0.51%)	1/402 (0.25%)
Acute Psychosis [A] †	2/391 (0.51%)	1/402 (0.25%)
Aggression [A] †	1/391 (0.26%)	1/402 (0.25%)
Agitation [A] †	3/391 (0.77%)	0/402 (0%)
Alcohol Abuse [A] †	1/391 (0.26%)	1/402 (0.25%)

	Quetiapine XR	Risperidone
	Affected/At Risk (%)	Affected/At Risk (%)
Anxiety [A] †	1/391 (0.26%)	0/402 (0%)
Confusional State [A] †	1/391 (0.26%)	0/402 (0%)
Delusion [A] †	0/391 (0%)	1/402 (0.25%)
Depression [A] †	2/391 (0.51%)	1/402 (0.25%)
Mental Disorder [A] †	1/391 (0.26%)	0/402 (0%)
Panic Attack [A] †	1/391 (0.26%)	0/402 (0%)
Psychotic Disorder [A] †	9/391 (2.3%)	5/402 (1.24%)
Schizoaffective Disorder [A] †	1/391 (0.26%)	1/402 (0.25%)
Schizophrenia [A] †	12/391 (3.07%)	5/402 (1.24%)
Schizophreniform Disorder [A] †	1/391 (0.26%)	0/402 (0%)
Suicidal Ideation [A] †	0/391 (0%)	1/402 (0.25%)
Suicide Attempt [A] †	3/391 (0.77%)	0/402 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Quetiapine XR	Risperidone
	Affected/At Risk (%)	Affected/At Risk (%)
Total	238/391 (60.87%)	258/402 (64.18%)
Gastrointestinal disorders		
Aptyalism [A] †	33/391 (8.44%)	21/402 (5.22%)
Constipation [A] †	40/391 (10.23%)	23/402 (5.72%)
Nausea [A] †	18/391 (4.6%)	26/402 (6.47%)
General disorders		

	Quetiapine XR	Risperidone
	Affected/At Risk (%)	Affected/At Risk (%)
Asthenia [A] †	22/391 (5.63%)	25/402 (6.22%)
Investigations		
Weight Increased [A] †	18/391 (4.6%)	25/402 (6.22%)
Nervous system disorders		
Dizziness Postural [A] †	23/391 (5.88%)	18/402 (4.48%)
Headache [A] †	23/391 (5.88%)	39/402 (9.7%)
Sedation [A] †	25/391 (6.39%)	15/402 (3.73%)
Somnolence [A] †	71/391 (18.16%)	47/402 (11.69%)
Tremor [A] †	7/391 (1.79%)	29/402 (7.21%)
Psychiatric disorders		
Anxiety [A] †	33/391 (8.44%)	38/402 (9.45%)
Insomnia [A] †	30/391 (7.67%)	52/402 (12.94%)
Tension [A] †	18/391 (4.6%)	20/402 (4.98%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator 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/Official Title: Gerard Lynch

Organization: AstraZeneca

Phone:

Email: clinicaltrialtransparency@astrazeneca.com