ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/24/2010

ClinicalTrials.gov ID: NCT00660595

Study Identification

Unique Protocol ID:	D1443L00042
Brief Title:	Study in Schizophrenic In-patients Treated With Quetiapine Prolong or Oral Risperidone at Flexible Dose
Official Title:	A Pilot Study of Three-Week, Randomised, Open Comparison in Schizophrenic In-patients Treated With Quetiapine Prolong or Oral Risperidone at Flexible Dose
Secondary IDs:	

Study Status

Record Verification:	August 2010
Overall Status:	Terminated
Study Start:	September 2008
Primary Completion:	December 2008 [Actual]
Study Completion:	December 2008 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	
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: 22/2008 Board Name: Pohjois-Savo hospital district, Kuopio University Hospital, Ethical Committee Board Affiliation: Pohjois-Savo hospital district, Kuopio University Hospital, Ethical Committee Phone: +358 17 173 311 Email: tuija.j.jussila@kuh.fi
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Finland: Finnish Medicines Agency

Study Description

Brief Summary:	This pilot trial in Finland is designed to evaluate in a randomized fashion change of agitation in acute schizophrenic patients (Schizophrenia or Schizoaffective psychosis or Schizophreniformic psychosis)Diagnostic and Statistical Manual (DSM - IV) with the first visits on days 1, 2, 4 or 5 and 7 ± 1.
Detailed Description:	

Conditions

Conditions:	Schizophrenic Disorders
Keywords:	Schizophrenia Schizoaffective psychosis Schizophreniformic psychosis Pilot study Quetiapine Prolong Risperidone

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:	Safety/Efficacy Study
Enrollment:	29 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Oral	Drug: Quetiapine Oral administration Other Names: • Seroquel
Active Comparator: 2 Oral	Drug: Risperidone Oral administration 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:

- In the opinion of the Investigator, requirement for treatment for an acute episode of schizophrenia, schizoaffective disorder or schizophreniformic psychosis (according to DSM-IV diagnostic criteria), Positive and Negative Symptoms Scale (PANSS) ≥ 65, CGI ≥ 4

Exclusion Criteria:

- Pregnancy or lactation
- In-patients/hospitalized > 7 days before enrollment
- Known intolerance or lack of response to quetiapine fumarate or risperidone, as judged by the investigator

Contacts/Locations

Study Officials: Yrjö Ovaskainen, MD
Study Director
AstraZeneca Finland

Hannu Koponen, MD, PhD
Study Principal Investigator
Kuopio University

Locations: Finland
Research Site
Harjavalta, Finland

Research Site
Helsinki, Finland

Research Site
Pitkaniemi, Finland

Research Site
Turku, Finland

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Two recruiting sites between 13 may 2008 and 28 Jan 2009: Aurora Hospital Helsinki and Pitkäniemi Hospital Tampere.

Pre-Assignment Details	Site 01 pre-screened 19 subjects, two were randomised, 12 did not consent to participate and five were not included due to other reasons.One subject completed the study and the other discontinued from the study on Day 2 (subject escaped from the hospital).Site 03 pre-screened 10 subjects, of which only one completed the study.

Reporting Groups

	Description
Seroquel	Quetiapine Prolong, oral administration
Risperdal	Risperidone, oral administration

Overall Study

	Seroquel	Risperdal
Started	19	10
Completed	1	1 [1]
Not Completed	18	9
Lost to Follow-up	0	1
Did not consent to participate in study	12	8
Participant left hospital	1	0
Non Specified reasons	5	0

[1] One of the two was lost to follow-up

Baseline Characteristics

Reporting Groups

	Description
Seroquel	Quetiapine Prolong, oral administration
Risperdal	Risperidone, oral administration

Baseline Measures

	Seroquel	Risperdal	Total
Number of Participants	19	10	29

	Seroquel	Risperdal	Total
Age, Continuous [units: years] Mean (Full Range)	47 (47 to 47)	51 (39 to 63)	49 (47 to 63)
Gender, Male/Female [1] [units: Participants]			
Female	1	1	2
Male	0	1	1

[1] randomised participants

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Positive and Negative Symptoms Scale, Excitatory Subscale (PANSS-EC) Score (Time Frame: 3 Weeks)
Measure Description	PANSS-EC score change was to be measured by calculating the difference between baseline score and 3 week's score. The PANSS-EC consists of 5 items (Poor IMpulse Control, Tension, Hostility, Uncooperativeness, and Excitement), each with associated descriptors. Each descriptor is rated on a 7 point scale from 1 = (absence of any symptom) to 7 = (extremely severe symptoms).
Time Frame	baseline and 3 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Seroquel	Quetiapine Prolong, oral administration
Risperdal	Risperidone, oral administration

Measured Values

	Seroquel	Risperdal
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Clinical Global Impression, Severity Scale (CGI-S) and in Absolute Clinical Global Impression, Improvement Scale (CGI-I) (Performed 4 Times/ 3 Weeks)
Measure Description	The CGI change was to be measured by calculating the difference between baseline score and 3 week's score. CGI-S Score of 1 = no illness to score of 7 = extremely ill. CGI-I Score of 1 =very much improved since the initiation of treatment to 7=very much worse since the initiation of treatment
Time Frame	baseline and 3 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Seroquel	Quetiapine Prolong, oral administration
Risperdal	Risperidone, oral administration

Measured Values

	Seroquel	Risperdal
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Overt Aggression Scale (OAS) (Performed 6 Times/ 3 Weeks)
Measure Description	The Overt Agression Scale (OAS) change was to be measured by calculating the difference between baseline score and 3 week's score. Score between 1 and 16 verbal aggression (OAS 1, score 1-4), physical aggression against objects (OAS 2, score 5-8), physical aggression against self (OAS 3, score 9-11) and physical aggression against other people (OAS 4, score 12-16).
Time Frame	baseline and 3 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Seroquel	Quetiapine Prolong, oral administration
Risperdal	Risperidone, oral administration

Measured Values

	Seroquel	Risperdal
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Total Positive and Negative Symptoms Scale (PANSS Score) (Performed 5 Times/ 3 Weeks)
Measure Description	PANSS score change was to be measured by calculating the difference between baseline score and 3 week's score. The PANSS consists of 7 positive and 11 negative items each with associated descriptors. Each descriptor is rated on a 7 point scale from 1=(absence of any symptom) to 7=(extremely severe symptoms).
Time Frame	baseline and 3 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Seroquel	Quetiapine Prolong, oral administration
Risperdal	Risperidone, oral administration

Measured Values

	Seroquel	Risperdal
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

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

Reporting Groups

	Description
Seroquel	Quetiapine Prolong, oral administration
Risperdal	Risperidone, oral administration

Serious Adverse Events

	Seroquel	Risperdal
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/1 (0%)	0/1 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Seroquel	Risperdal
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/1 (0%)	1/1 (100%)
Endocrine disorders		
Elevated Prolactin Level [A] †	0/1 (0%)	1/1 (100%)
Musculoskeletal and connective tissue disorders		
Muscle spasms [A] †	0/1 (0%)	1/1 (100%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, ICD.10

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

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