ISRCTN97049967 https://doi.org/10.1186/ISRCTN97049967

Phase 3 long-term safety, tolerability and effectiveness of lurasidone in subjects with schizophrenia or schizoaffective disorder

Submission date	Recruitment status	[X] Prospectively registered
11/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/03/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00641745

Protocol serial number
D1050237

Study information

Scientific Title
Phase 3 long-term safety, tolerability and effectiveness of lurasidone in subjects with schizophrenia or schizoaffective disorder: a randomised, active comparator-controlled trial

Study objectives
To assess long-term safety, tolerability and effectiveness of lurasidone over a 12-month double-blind period in clinically stable out-patients with chronic schizophrenia or schizoaffective disorder, followed by a 6-month open label extension phase. Risperidone will be used as active comparator.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Argentina: Ethics Committee for Research on Mental Illness (Comite de Bioetica e Investigacion-Funacion para el Estudio y Tratamiento de las Enfermedades Mentales). Date of approval: 13/03/2008
Brazil: Ethics committee for Research at the Mario Kroeff Hospital (Comite de Etica em Pesquisa de Hospital Mario Kroeff). Date of approval: 28/02/2008
Chile: Ethics Committee of the South Metropolitan Health Service (Comite Etico-Cientifico Servidio de Salud Metropolitano Sur). Date of approval: 19/03/2008
South Africa:
1. Ethics Committee, University of the Free State. Date of approval: 11/03/2008 (ref: ETOVS NR51/08)
2. Ethics Committee, Pharma-Ethics (Pty), Ltd. Date of approval: 16/04/2008 (ref: 08032544)
Thailand: The Ethical Review Committee for Research in Human Subjects. Date of approval: 08/04/2008

Ethics approval pending from:
Croatia: Central Ethics Committee. Approval expected on 30/08/2008
Israel: Helsinki Committee of the Shalvata Mental Health Centre. Approval expected on 16/04/2008

Study design
Randomised active-comparator controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
This trial is in two stages: 12-month double-blind treatment of lurasidone HCl 40 mg oral tablets with matching placebo, and risperidone over-encapsulated oral capsules (2, 4 or 6 mg) with matching placebo in double-dummy design. Once-daily dosing for all medications (Stage 1).

Followed by 6-month open-label extension phase (Stage 2). During the open-label period all participants will (after a single-blind, 3 day placebo washout) initially receive lurasidone HCl 80 mg/day, after 7 days of study medication the dose may be adjusted between 40-120 mg/day.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Lurasidone, risperidone

Primary outcome(s)
Assess long-term safety and tolerability of lurasidone by measuring proportion of subjects with adverse events and serious adverse events. These will be assessed at 12 months. Safety will also be assessed at 18 months.

Key secondary outcome(s))
1. To measure changes in the following:
1.1. Weight at Screening, baseline, Week 12, Month 6, 9 and 12 and then monthly until 18 months
1.2. BMI at Screening, baseline, Week 12, Month 6, 9 and 12 and then monthly until 18 months
1.3. Waist circumference at baseline, 6, 12 and 18 months
1.4. Serum prolactin at Screening, baseline, 6 and 12 weeks, 6, 12, 13, 15 and 18 months
1.5. Testosterone at baseline, 6 and 12 weeks, 6, 12, 15 and 18
1.6. N-telopeptide (NTx) at Screening, baseline, 6, 9, 12, 15 and 18 months
1.7. Osteocalcin at Screening, baseline, 6, 9, 12, 15 and 18 months
1.8. Bone alkaline phosphatise at Screening, baseline, 6, 9, 12, 15 and 18 months
1.9. Parathyroid hormone (PTH) at Screening, baseline, 6, 9, 12, 15 and 18 months
1.10. ECG parameters at Screening, baseline, 7 days, 6 weeks, 6, 12 and 18 months
2. To evaluate long-term efficacy of lurasidone and risperidone by changes in the following at 12 months:
2.1. Positive and Negative Symptom Scale (PANSS) score
2.2. Clinical global impression of severity (CGI-S) score
2.3. Montgomery and Asberg Depression Rating Scale (MADRS) score
3. Demonstrate lurasidone is as effective as risperidone in maintaining clinical stability and preventing relapse, assessed at 12 months

Completion date
06/05/2010

Eligibility

Key inclusion criteria
1. Aged between 18 and 75 years, both genders
2. Meets the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV) criteria for a primary diagnosis of schizophrenia
3. Judged by investigator to be clinically stable 8 weeks prior to baseline
4. Not pregnant, if of reproductive potential agrees to remain abstinent or use adequate and reliable contraception for duration of study
5. Tests negative for drug abuse at screening

6. Good physical health on the basis of medical history, physical examination and laboratory screening
7. Willing and able to comply with the protocol, including the inpatient requirements and outpatient visits
8. Provides written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Clinically significant medical condition that would pose a risk to subject in the study
2. Type 1 diabetes and insulin-dependent Type 2 diabetes
3. Chronic organic disease of the central nervous system
4. History of head injury resulting in attributable neuropsychiatric systems
5. History of malignancy <5 years prior to signing informed consent
6. Clinically significant history of alcohol abuse/alcoholism or drug abuse/dependence within last 6 months
7. History of macular or retinal pigmentary disease
8. History of stomach or intestinal surgery
9. History of previous psychosurgery
10. History of neuroleptic malignant syndrome
11. Severe tardive dyskinesia, severe chronic tardive dystonia or other severe chronic movement disorder
12. Clinically significant suicidal ideation, suicidal behaviour or violent behaviour in past 6 months.
13. Body mass index <18.5 or >40 kg/mg^2
14. Evidence of acute hepatitis, clinically significant chronic hepatitis or impaired hepatic function
15. Prolactin concentration >100 ng/mL at screening
16. Abnormal laboratory parameters indicating clinically significant medical condition
17. Resistant to antipsychotic treatment
18. Treatment with risperidone within 6 weeks prior to baseline
19. History of poor response to risperidone
20. Electroconvulsive therapy treatment within last 3 months or likely to require it during study
21. History of treatment with clozapine for refractory psychosis or clozapine treatment within 4 months of baseline visit
22. Treatment with mood stabilisers or antidepressants with 1 week, fluoxetine within 1 month

23. Received depot neuroleptics unless last injection at least 1 treatment cycle before randomisation
24. Subject does not require chronic treatment with antipsychotic drug
25. Subject has condition, therapy, laboratory abnormality which may affect results of /participation in study
26. History of hypersensitivity to risperidone
27. History or presence of abnormal electrocardiogram (ECG) which is clinically significant
28. Participation in study with investigational compound/device within 30 days of signing informed consent
29. Donation of blood products or has had phlebotomy of >300 mL within 8 weeks of signing informed consent
30. Previously screened or entered into antipsychotic medication withdrawal phase of this study more than 3 times
31. Routinely use anabolic steroids or require ongoing treatment with steroids
32. Past or current Cushing's disease, Addison's disease, growth hormone deficiency, hyperparathyroidism
33. Unlikely to adhere to study procedures, in investigator's opinion

Date of first enrolment
16/05/2008

Date of final enrolment
06/05/2010

Locations

Countries of recruitment
United Kingdom

England

Argentina

Brazil

Chile

Croatia

Israel

South Africa

Thailand

Study participating centre

Dainippon Sumitomo Pharma Europe Ltd
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Sponsor information

Organisation
Dainippon Sumitomo Pharma America Inc. (USA)

ROR
https://ror.org/04vwbmb32

Funder(s)

Funder type
Industry

Funder Name
Dainippon Sumitomo Pharma Co. Ltd (Japan)

Alternative Name(s)
Dainippon Sumitomo Pharma Co., Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No
Basic results				No	No