ISRCTN44297014 https://doi.org/10.1186/ISRCTN44297014

A phase III randomised, double-blind, active comparator-controlled clinical trial to study the safety and efficacy of lurasidone in subjects with schizophrenia (PEARL 3 extension study)

Submission date
14/11/2008

Recruitment status
No longer recruiting

Registration date
26/05/2009

Overall study status
Completed

Last Edited
26/05/2009

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D1050234

Study information

Scientific Title

Acronym
PEARL 3 Extension Study

Study objectives
Lurasidone HCl is a compound being developed for the treatment of schizophrenia. This clinical study is designed to test the hypothesis that lurasidone is effective, tolerable, and safe as compared with quetiapine XR long-term among schizophrenic outpatients with chronic schizophrenia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
USA: Copernicus Group IRB, approved on 05/09/2008.

All other centres will seek ethics approval before recruitment of the first participant.

Study design
Randomised double-blind active comparator-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions

Subjects who meet entry criteria will continue treatment with either flexibly dosed lurasidone or quetiapine XR based on their treatment assignment in Study D1050233 in a double-blinded fashion. Subjects treated with placebo in Study D1050233 will be treated with lurasidone.

Arm 1: Lurasidone HCl 40-160 mg/day orally for 12 months
Arm 2: Quetiapine XR 200-800 mg/day orally for 12 months

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Lurasidone HCl, quetiapine XR

Primary outcome measure
1. Primary efficacy endpoint:
1.1. Time to relapse of psychotic symptoms in subjects to measure the long-term maintenance of antipsychotic efficacy of lurasidone compared with quetiapine XR.

2. Primary safety endpoints:
The proportion of subjects with:
2.1. Adverse Events (AEs)
2.2. Discontinuations due to AEs
2.3. Serious Adverse Events (SAEs)

AEs will be monitored throughout the study until Month 12.

Secondary outcome measures
Efficacy endpoints of interest:
Time to relapse of psychotic symptoms. Mean change from D1050233 baseline in the Positive and Negative Syndrome Scale (PANSS): positive score, negative score, and excitability score. PANSS will be carried out at Month 3, 6, 9, 12 in this extension study.

Overall study start date
01/12/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria
Screening for the present study will take place after subjects' participation in Study D1050233 has been completed, and after providing informed consent.

Principal inclusion criteria:
1. Males and females 18-75 years of age inclusive

2. Provide written informed consent
3. Completed all required assessments on the final study visit in Study D1050233
4. Suitable for treatment in an outpatient setting

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Approximately 240

Key exclusion criteria
1. Any chronic organic disease of the central nervous system (CNS) (other than schizophrenia)
2. Considered by the investigator to be at imminent risk of suicide or injury to self, others, or property

Date of first enrolment
01/12/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Colombia

Germany

India

Philippines

Romania

Russian Federation

Ukraine

United States of America

Study participating centre
Dainippon Sumitomo Pharma America Inc.
New Jersey
United States of America
07024

Sponsor information

Organisation
Dainippon Sumitomo Pharma America Inc. (USA)

Sponsor details
One Bridge Plaza
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New Jersey
United States of America
07024

Sponsor type
Industry

Website
http://www.ds-pharma.co.jp/english

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration