

Safety and efficacy trial of two doses of lurasidone in acutely psychotic subjects with schizophrenia (PEARL 3)

Submission date 14/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/04/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Kaushik Sarma

Contact details
Dainippon Sumitomo Pharma America Inc.
One Bridge Plaza
Suite 510
Fort Lee
New Jersey
United States of America
07024

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00790192

Protocol serial number
D1050233

Study information

Scientific Title

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

Acronym

PEARL 3

Study objectives

Lurasidone HCl is a compound being developed for the treatment of schizophrenia. The clinical study is designed to test the hypothesis that lurasidone is effective, tolerable and safe as compared with quetiapine XR short-term among acutely psychotic patients 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 placebo- and active comparator-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

There is a 14-day screening period and a 3 to 7-day placebo washout period before randomisation of the participants for the trial.

Patients will be randomly assigned to one of the four treatment arms in equal numbers:

Arm 1: Lurasidone HCl 80 mg/day orally for 6 weeks

Arm 2: Lurasidone HCl 160 mg/day orally for 6 weeks

Arm 3: Quetiapine XR 600 mg/day for 6 weeks

Arm 4: Placebo for 6 weeks

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Lurasidone, quetiapine

Primary outcome(s)

Primary Efficacy Endpoint:

Mean change from baseline in total Positive and Negative Syndrome Scale (PANSS) score at endpoint (Week 6).

Primary Safety Endpoints:

The proportion of subjects with the following at Week 6:

1. Adverse Events (AEs)
2. Discontinuations due to AEs
3. Serious Adverse Events (SAEs)

Key secondary outcome(s)

Key secondary efficacy endpoints:

Mean change from baseline in:

1. Clinical Global Impressions Severity (CGI-S) score, assessed at baseline, Day 4, then every week until Week 6
2. PANSS total score, assessed at baseline, Day 4, then every week until Week 6

Completion date

12/12/2009

Eligibility

Key inclusion criteria

1. Provide written informed consent and aged between 18 and 75 years of age (both males and females are eligible)
2. Meets DSM-IV™ criteria for a primary diagnosis of schizophrenia
3. Not pregnant, if of reproductive potential agrees to remain abstinent or use adequate and reliable contraception for duration of study
4. Able and agrees to remain off prior antipsychotic medication for the duration of study
5. Good physical health on the basis of medical history, physical examination, and laboratory screening
6. Willing and able to comply with the protocol, including the inpatient requirements and outpatient visits

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Considered by the investigator to be at imminent risk of suicide or injury to self, others, or property
2. Any chronic organic disease of the central nervous system (CNS) (other than schizophrenia)
3. Used investigational compound within 30 days
4. Clinically significant or history of alcohol abuse/alcoholism or drug abuse/dependence within the last 6 months

Date of first enrolment

15/10/2008

Date of final enrolment

12/12/2009

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)

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	01/11/2013	10/04/2019	Yes	No
Results article	results	01/08/2015	10/04/2019	Yes	No
Basic results				No	No