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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

Registration date
26/05/2009

Overall study status
Completed

Last Edited
10/04/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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)
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.

Primary study design
Interventional

Study design
Randomised double-blind placebo- and active comparator-controlled trial

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