

A phase three randomised, placebo-controlled, clinical trial to study the safety and efficacy of three doses of lurasidone hydrochloride (HCl) in acutely psychotic patients with schizophrenia

Submission date 06/02/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 21/04/2008	Overall study status Completed	☐ Protocol
Last Edited 22/03/2016	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00549718

Protocol serial number

D1050229

Study information

Scientific Title

A phase three randomised, placebo-controlled, clinical trial to study the safety and efficacy of three doses of lurasidone hydrochloride (HCl) in acutely psychotic patients with schizophrenia

Study objectives

Lurasidone HCl demonstrates greater efficacy, safety and tolerability in acutely psychotic patients with schizophrenia as compared to placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. India: Ethics Committee, Seth Vadilal Sarabhai General Hospital, 04/04/2008
2. Romania: National Ethics Committee, 21/02/2008
3. Russia: Ethics Committee at the Federal Service on Surveillance in Healthcare and Social Development of Russian Federation, 19/02/2008
4. Ukraine: Central Ethics Commission, 07/02/2008
5. France: CPP Sud Méditerranée III Ethics Committee, 16/04/2008

Ethics approval expected from:

6. Malaysia: Medical Research and Ethics Committee; submitted 27/12/2007, expected approval date: 10/03/2008

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Six-week, randomised, double-blind multi-centre, parallel-group study to evaluate efficacy and safety of three doses of lurasidone HCl compared with placebo (oral use film-coated tablet). After 14 day screening period and seven-day placebo washout period, patients are randomly assigned to one of four treatment arms (lurasidone HCl 40 mg/day, 80 mg/day or 120 mg/day or placebo [1:1:1 ratio]). Patients randomised to lurasidone HCl 120 mg/day will take lurasidone HCl 80 mg for days 1 - 3 then 120 mg for remainder of study. Option to continue in 22-month open-label extension phase.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Lurasidone hydrochloride (HCl)

Primary outcome(s)

Change in total positive and negative syndrome scale (PANSS) score from baseline to the end of the double blind treatment period (six weeks).

Key secondary outcome(s)

Clinical global impression of severity (CGI-S) from baseline to the end of the double-blind treatment (six weeks).

Completion date

31/07/2011

Eligibility**Key inclusion criteria**

1. Provide written informed consent and aged between 18 and 75 years of age, either sex
2. Meets Diagnostic and Statistical Manual of Mental Disorders, 4th edition (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

01/11/2007

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

United Kingdom

England

France

India

Malaysia

Romania

Russian Federation

Ukraine

United States of America

Study participating centre

Dainippon Sumitomo Pharma Europe Ltd (Europe)

London

United Kingdom

SW1E 6QT

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	01/05/2013		Yes	No
Basic results				No	No