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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

Registration date
21/04/2008

Overall study status
Completed

Last Edited
22/03/2016

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

Contact name
Dr Shelda Alcock

Contact details
Dainippon Sumitomo Pharma Europe Ltd (Europe)
First Floor, Southside
97-105 Victoria Street
London
United Kingdom
SW1E 6QT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00549718

Secondary identifying numbers
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

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

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

Overall study start date
01/11/2007

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 480 patients

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/alchoholism 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
England

France

India

Malaysia

Romania

Russian Federation

Ukraine

United Kingdom

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)

Sponsor details
One Bridge Plaza
Suite 510
Fort Lee
New Jersey
United States of America
07024

Sponsor type
Industry

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Results article	results	01/05/2013		Yes	No