

A phase 3 randomised placebo- and active comparator-controlled, clinical trial to study the safety and efficacy of two doses of lurasidone HCL in acutely psychotic patients with schizophrenia

Submission date 26/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/08/2021	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
Ms Shelda Alcock

Contact details
Dainippon Sumitomo Pharma Europe Ltd
First Floor
Southside
97-105 Victoria Street
London
United Kingdom
SE1E 6QT

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00615433

Protocol serial number

Study information

Scientific Title

A phase 3 randomised placebo- and active comparator-controlled, clinical trial to study the safety and efficacy of two doses of lurasidone HCL in acutely psychotic patients with schizophrenia

Study objectives

Lurasidone HCL demonstrates greater efficiency, safety and tolerability in acutely psychotic patients with schizophrenia as compared with placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. Bulgaria: Multicentre trials Ethics Committee (MEC), 29/04/2008
2. Colombia: Research Ethics Committee (Comite de Etica en Investigacion Servicios Psiquiatricos S.A.), 12/02/2008
3. Lithuania: Central EC, Lithuania Bioethics Committee, 27/02/2008
4. Serbia: Ethics Committee of Clinical Centre of Serbia, 12/02/2008

Ethics approval pending from:

5. India: Ethics Committee of the Hospital for Mental Health. Expected approval date: 30/04/2008
6. Peru: Research Ethics Committee (Comite de Etica en Investigacion Hospital Nacional Guillermo Almenara). Expected approval date: 20/04/2008
7. Philippines: National Ethics Committee/National Centre for Mental Health. Expected approval date: 29/06/2008

Study design

Randomised double-blind parallel-group study

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 7-day placebo washout period before randomisation of the participants for the acute phase of the trial.

Acute phase:

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

Arm 1: Lurasidone HCl 40 mg/day orally for 6 weeks
Arm 2: Lurasidone HCl 120 mg/day orally for 6 weeks
Arm 3: Olanzapine 15 mg (oral use film-coated tablet/capsule) for 6 weeks
Arm 4: Placebo for 6 weeks

Open label extension phase:

All participants who complete the 6-week acute phase will be given treatment with open label lurasidone HCl (oral) for 6 months.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Lurasidone, olanzapine

Primary outcome(s)

Change in total PANSS (the Positive And Negative Syndrome Scale) score from baseline to the end of the 6-week double-blind treatment period.

Key secondary outcome(s)

Clinical Global Impressions - Severity (CGI-S) from baseline to the end of the double-blind treatment.

Completion date

30/10/2009

Eligibility

Key inclusion criteria

1. Aged between 18 and 75 years of age, both genders
2. Those who provide written informed consent
3. Meets Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM IV) criteria for a primary diagnosis of schizophrenia
4. Not pregnant; if of reproductive potential agrees to remain abstinent or use adequate and reliable contraception for duration of study
5. Able and agrees to remain off prior antipsychotic medication for the duration of study
6. Good physical health on the basis of medical history, physical examination, and laboratory screening
7. 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

01/01/2008

Date of final enrolment

30/10/2009

Locations**Countries of recruitment**

United Kingdom

England

Bulgaria

Colombia

India

Lithuania

Peru

Philippines

Serbia

Study participating centre

Dainippon Sumitomo Pharma Europe Ltd

London

United Kingdom

SE1E 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?
Basic results		14/02/2011		No	No