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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	Recruitment status	[ ] Prospectively registered
26/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/08/2021	Mental and Behavioural Disorders	

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

D1050231

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 HCI 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-bind 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes