

# 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

<b>Submission date</b> 26/02/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/08/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

NCT00615433

**Secondary identifying numbers**

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

**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**

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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/01/2008

## **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

**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/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**

Bulgaria

Colombia

England

India

Lithuania

Peru

Philippines

Serbia

United Kingdom

**Study participating centre**

**Dainippon Sumitomo Pharma Europe Ltd**

London

United Kingdom

SE1E 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?
<a href="#">Basic results</a>		14/02/2011		No	No