

The effect of varying degrees of hepatic impairment on the single dose pharmacokinetic profile of orally administered lurasidone: a phase I study

Submission date 29/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/08/2011	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

Secondary identifying numbers

Study information

Scientific Title

The effect of varying degrees of hepatic impairment on the single dose safety and pharmacokinetic profile of lurasidone: an open-label phase I single dose non-randomised oral administration study

Study objectives

Primary: to assess the effect of varying degrees of hepatic impairment on the pharmacokinetics of lurasidone

Secondary: to assess the effect of varying degrees of hepatic impairment on the safety of lurasidone

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Czech Republic: Ethics Committee for Clinical and Experimental Medicine and Faculty Thomayer Hospital approved 6th November 2008
2. Slovak Republic: Ethics Committee FNsP Bratislava approved 28th October 2008

Study design

Open-label phase I single dose non-randomised oral administration study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Hepatic impairment

Interventions

All patients will receive a single oral 20 mg dose of lurasidone and be followed up for 9 days.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Lurasidone

Primary outcome measure

Pharmacokinetics will be assessed as follows:

1. Primary parameters: AUC_{0-last}, C_{max}, calculated once at the completion of the trial, using data from blood samples collected from dosing up to 168 hours post-dose
2. Secondary parameters: AUC₀₋₈, CL/F, t_{max}, t_{1/2}, V_z/F and λ_z, collected once at the completion of the trial, using data from blood samples collected from dosing up to 168 hours post-dose

Secondary outcome measures

Safety will be assessed by using the following endpoints:

1. Spontaneous adverse event reporting
2. Clinical laboratory tests (clinical chemistry including prolactin, haematology including coagulation, and urinalysis)
3. Concomitant medication review
4. Vital sign assessments (supine blood pressure, heart rate, and body temperature)
5. 12-lead ECG
6. Complete physical examinations

Collected once at the completion of the trial, using data from blood samples collected from dosing up to 168 hours post-dose.

Overall study start date

12/11/2008

Completion date

31/03/2009

Eligibility

Key inclusion criteria

Main criteria:

1. Subject is male or female
2. Subject is between 18 to 75 years of age, inclusive
3. Body mass index (BMI) between 18 to 34 kg/m², inclusive, and a minimum body weight of 50 kg
4. Subject is informed of the nature of the study and has given written consent prior to initiating any study procedure
5. Subjects able to comply with all aspects of the protocol

Hepatic impairment subjects:

6. Subjects with Child-Pugh Clinical Assessment Score consistent with degree of hepatic impairment
7. Subject's hepatic disease is deemed stable by the Investigator

8. Subject's pre-study clinical laboratory findings are within normal range or if outside of the normal range, deemed associated with underlying hepatic dysfunction or not clinically significant in the opinion of the Investigator

Normal hepatic function subjects:

9. Subject is considered to be in good health in the opinion of the Investigator, as determined by medical history, physical examination, vital signs, electrocardiogram (ECG), and standard laboratory tests

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

15 - 18 patients with hepatic impairment; 6 healthy subjects; minimum 21 in study

Key exclusion criteria

1. Subject has had a clinically significant intercurrent illness in the four weeks before screening
2. Subject shows evidence of a clinically significant underlying medical condition, that, in the opinion of the Investigator, would represent a risk of study participation
3. History of or suspicion of significant gastrointestinal bleeding within the preceding 2 months
4. Any disorder (other than hepatic impairment, appendectomy, and cholecystectomy) that may alter the absorption, distribution, metabolism or excretion of drugs
5. History of clinically significant drug allergy including a history of atopic allergy (asthma, urticaria, or eczematous dermatitis)
6. Pregnant or lactating female subjects

Date of first enrolment

12/11/2008

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

Czech Republic

England

Slovakia

United Kingdom

Study participating centre

Dainippon Sumitomo Pharma Europe Ltd

London

United Kingdom

SW1E 6QT

Sponsor information

Organisation

Dainippon Sumitomo Pharma Europe Ltd (UK)

Sponsor details

1st Floor, Southside

97 - 105 Victoria Street

London

United Kingdom

SW1E 6QT

Sponsor type

Industry

Website

<http://www.ds-pharma.co.jp/english>

ROR

<https://ror.org/03sh4z743>

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