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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	[_] Prospectively registered [_] Protocol
Registration date 20/04/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/08/2011	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

D1050264

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: AUC0-last, Cmax, 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, tmax, t½, Vz/ F and λz, 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/m^2, 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
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Sponsor information

Organisation
Dainippon Sumitomo Pharma Europe Ltd (UK)

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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