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

Submission date	Recruitment status	[_] Prospectively registered
22/10/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/02/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/02/2009	Urological and Genital Diseases	[_] 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

D1050265

Study information

Scientific Title

Study objectives
Primary hypothesis:
To assess the effect of varying degrees of renal impairment on the pharmacokinetics of lurasidone and its major metabolites.

Secondary hypothesis:
To assess the effect of varying degrees of renal impairment on the safety of lurasidone and its major metabolites.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Germany: Medical Association of Saxony gave approval on the 29th August 2008
2. Czech Republic: Ethics Committee for Multi-Centric Clinical Trial of the University Hospital Motol gave approval on the 23rd September 2008

Study design
Open-label single dose oral administration study

Primary study design
Interventional

Secondary study design
Non 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
Renal impairment

Interventions
All patients will receive a single oral 40 mg dose of lurasidone and be followed up for 7 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, assessed by PK sampling at 15 timepoints from 0 - 96 hours post-dose
2. Secondary parameters: AUC0-8, CL/F, tmax, t½, Vz/F and lambda z assessed at multiple timepoints until day 7

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 and urinalysis)
3. Concomitant medication review
4. Vital sign assessments (supine blood pressure, heart rate, body temperature)
5. 12-lead ECG
6. Complete physical examinations

Overall study start date
01/10/2008

Completion date
31/12/2008

Eligibility

Key inclusion criteria
All subjects:
1. Male or female, between 18 and 75 years of age inclusive
2. Body mass index (BMI) between 18 and 32 kg/m^2, and minimum body weight of 50 kg
3. Written informed consent
4. Able to comply with all aspects of protocol

Renal impairment subjects:
5. Renal impairment based on Cockcroft-Gault estimation of creatinine clearance (CrCl)
6. Renal disease is deemed stable by investigator
7. Pre-study clinical laboratory findings are within normal range

Normal renal function subjects:
8. Subject has normal renal function based on Cockcroft-Gault estimation
9. Subject is in good health 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
24 - 27 patients (with renal impairment); minimum of 9 patients (control group); minimum of 33 (total study)

Key exclusion criteria
1. Clinically significant illness in 4 weeks before screening
2. Shows evidence of clinical significant underlying medical condition
3. End-stage renal disease and is receiving dialysis
4. Any disorder which may alter drug absorption, distribution, metabolism and excretion

Date of first enrolment
01/10/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Czech Republic

England

Germany

United Kingdom

Study participating centre
Dainippon Sumitomo Pharma Europe Ltd
London
United Kingdom
SE1E 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