

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

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| Submission date 22/10/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 19/02/2009 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 19/02/2009 | Condition category Urological and Genital Diseases | <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

Protocol serial number

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

Primary study design

Interventional

Study design

Open-label single dose oral administration study

Study type(s)

Treatment

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(s)

Pharmacokinetics will be assessed as follows:

1. Primary parameters: AUC_{0-last}, C_{max}, assessed by PK sampling at 15 timepoints from 0 - 96 hours post-dose
2. Secondary parameters: AUC₀₋₈, CL/F, t_{max}, t_{1/2}, V_z/F and lambda z assessed at multiple timepoints until day 7

Key secondary outcome(s)

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

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/m², 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Czech Republic

Germany

Study participating centre

Dainippon Sumitomo Pharma Europe Ltd

London

United Kingdom

SE1E 6QT

Sponsor information

Organisation

Dainippon Sumitomo Pharma Europe Ltd (UK)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration