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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**
22/10/2008

**Recruitment status**
No longer recruiting

**Registration date**
19/02/2009

**Overall study status**
Completed

**Last Edited**
19/02/2009

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

**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

## Study design
Open-label single dose oral administration study

## Primary study design
Interventional

## 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: 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

## 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/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

### 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