Metabolic drug interaction profile of Silexan in vivo

Submission date 19/10/2009	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date	Overall study status	Statistical analysis plan
08/12/2009	Completed	[_] Results
Last Edited 08/12/2009	Condition category Other	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Prof Uwe Fuhr

Contact details Wevertal 76

Cologne Germany 50931

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 750201.01.08

Study information

Scientific Title

Single centre, double-blind, randomised, placebo-controlled, two-fold cross-over, drug cocktail phenotyping study on the in vivo interaction potential of Silexan (WS® 1265) with respect to the activities of cytochrome P-450 enzymes (CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4) in healthy volunteers

Study objectives

The objective of the study is to assess the interaction potential of Silexan (WS® 1265) 160 mg once daily administration (s.i.d.) with respect to the activities of CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The local medical ethics committee (Ethikkommission der Ärztekammer Nordrhein) approved on the 18th September 2009 (ref: 2009263)

Study design

Single centre double-blind randomised placebo-controlled cross-over comparative interaction study

Primary study design

Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s)

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

Activities of cytochrome P-450 enzymes

Interventions

Silexan (WS® 1265) 160 mg soft gelatine capsule or placebo for 11 days each. There is a screening visit within 14 days before the first intake of study drug; 11 days of treatment (cross-over period 1); a wash out period of 3 weeks; 11 days treatment (cross-over period 2); and a follow up visit within 4 - 10 days after last intake of study drug.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Silexan (WS® 1265)

Primary outcome measure

- 1. CYP1A2 as quantified using AUC0-t of caffeine in plasma
- 2. CYP2C9 as quantified using AUC0-t of tolbutamide in plasma
- 3. CYP2C19 as quantified using AUC0-t of omeprazole in plasma
- 4. CYP2D6 as quantified using AUC0-t of dextromethorphan in plasma
- 5. CYP3A4 as quantified using AUC0-t of midazolam in plasma

All measured on day 11 to day 12: 17 blood collections from 0 - 24 hours.

Secondary outcome measures

1. Pharmacokinetic parameters of the phenotyping substances

2. Safety parameters

All measured on day 11 to day 12: 17 blood collections from 0 - 24 hours.

Overall study start date

14/10/2009

Completion date

23/12/2009

Eligibility

Key inclusion criteria

- 1. Willing and capable to confirm written consent
- 2. Caucasian male or female
- 3. Aged between 18 55 years
- 4. A body mass index (BMI) 19 29 kg/m^2
- 5. Healthy

6. Non-pregnant and non-lactating, and have a negative urine pregnancy test result if subject is female

7. Use reliable contraception, i.e. two methods simultaneously if subject is female and of childbearing potential

Participant type(s)

Patient

Age group

Adult

Lower age limit 18 Years

Sex Both

Target number of participants

16

Key exclusion criteria

1. Subjects with any relevant clinical abnormality

2. Subjects with a tendency to loose stools and/or subjects with the history of a relevant surgical abdominal intervention

3. Subjects with any cardiac arrhythmia, subjects with acute infections within the last two weeks

4. Subjects with a history of any allergic disease with clinical signs

5. Subjects with suspicion of hypersensitivity to the investigational medication

6. Subjects with a history of severe skin reactions

7. Subjects receiving any medication within 2 weeks prior to study start or during the study

8. Subjects who have taken a drug with a long half-life (greater than 24 hours) within four weeks before the first trial day

9. Subjects who received chronic drug treatment (greater than 3 days) within eight weeks before the first trial day

10. Subjects who donated blood within the last 4 weeks before the start of the present study

11. Actual smokers defined as subjects who smoked any cigarette during the last three months

12. Subjects who are known or suspected to be (social) drug dependent

13. Subjects with a history of alcohol or recreational drug addiction

14. Subjects with positive drug screening tests

15. Subjects who are not willing or able to abstain from alcohol, methylxanthine-containing beverages and foods, and grapefruit flesh/juice from 1 week prior to the study until the safety follow-up examination

16. Anticipated problems of successfully placing an indwelling venous catheter at both forearms

Date of first enrolment

14/10/2009

Date of final enrolment

23/12/2009

Locations

Countries of recruitment Germany

Study participating centre Weyertal 76 Cologne Germany

Germany 50931

Sponsor information

Organisation

Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Sponsor details

Willmar-Schwabe-Strasse 4 Karlsruhe Germany 76227

Sponsor type

Industry

Website http://www.schwabepharma.com/international/

ROR https://ror.org/043rrkc78

Funder(s)

Funder type Industry

Funder Name Dr. Willmar Schwabe GmbH & Co. KG (Germany)

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