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Metabolic drug interaction profile of Silexan in vivo

Submission date	Recruitment status	[ ] Prospectively registered
19/10/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/12/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/12/2009	Other	[ ] 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
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)
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
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
50931

Sponsor information

Organisation

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

Sponsor details
Willmar-Schwabe-Strasse 4
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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