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Exploratory study to assess the cerebral bioavailability of Silexan® WS® 1265 standard softgel capsule and Silexan® WS® 1265 enteric-coated capsule using quantitative Electroencephalography (EEG) in healthy volunteers

Submission date
08/02/2011

Recruitment status
No longer recruiting

Registration date
18/03/2011

Overall study status
Completed

Last Edited
18/03/2011

Condition category
Mental and Behavioural Disorders

[ ] 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
750201.01.025

Study information

Scientific Title
Exploratory study to assess the cerebral bioavailability of Silexan® WS® 1265 standard softgel capsule and Silexan® WS® 1265 enteric-coated capsule using quantitative Electroencephalography (EEG) in healthy volunteers: a single-centre, randomised, double-blind, placebo-controlled, crossover study

Acronym
Silexan® (WS® 1265): EEG

Study objectives
To assess the influence of Silexan® (Silexan WS® 1265 standard softgel capsule part 1 and Silexan® WS® 1265 enteric-coated capsule part 2) on electric power of six defined frequency ranges with respect to 17 electrode positions during pharmaco electroencephalography in combination with psychometry. Investigation of bioavailability of Silexan® to the brain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the State Medical Board of Hessen (Ethik-Kommission bei der Landesärztekammer Hessen) approved on 8th February 2011

Primary study design
Interventional

Study design
Single-centre randomised double-blind placebo-controlled crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety disorder

Interventions
Cross-over with 3 sequences and 3 periods (part1: Silexan® WS® 1265 standard softgel capsule 80mg, 160mg , placebo; part2: Silexan® WS® 1265 enteric-coated capsule: 80mg, 160mg, placebo).
Each sequence for 14 days; one capsule once a day.
First administration at day 1 of each sequence before EEG sessions every hour until 4 hours after administation; then drugs are dispensed for the following 14 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Silexan® (Silexan WS® 1265 standard softgel capsule , Silexan® WS® 1265 enteric-coated capsule

Primary outcome(s)
Outcome variables describing the bio-availability of Silexan® to the brain

1. Quantitative source density EEG: electric power (V2) within the six frequency ranges (delta, theta, alpha1, alpha2, beta1 and beta2) for each of the 17 electrode positions (102 variables). The variables are assessed for recording condition "eyes open" and "eyes closed" separately. Electrode positions from two different brain regions of interest (ROI) (fronto-temporal delta and theta power and centro-parietal alpha1,2 and beta1,2 power) are grouped and averaged together to give a total of six parameters (one for each frequency) for the recording condition of three challenges: performance of the d2-test, the concentration performance test CPT (under stress) and the memory test. Thus, 18 parameters will be assessed for the recordings during mental challenges. All parameters are assessed 1 - 4 hours after administration as difference to absolute power of pre-drug values (which are set to 100%).

2. Outcome variables of psychometry
2.1. Attention-Load-Test (d2-Test)
2.2. Concentration-Performance-Test (CPT)
2.3. Memory Test (ME)

3. Outcome variables of safety
3.1. Adverse events
3.2. Laboratory tests

Key secondary outcome(s)
No secondary outcome measures

Completion date
30/10/2011

Eligibility

Key inclusion criteria
1. Male or female outpatients aged 18 to 65 years (both inclusive)
2. Written informed consent in accordance with the legal requirement
3. Readiness and ability on the part of the patient to comply with the physicians instructions and to fill in the self-assessment scales
4. Negative pregnancy test within 7 days before baseline visit in women with childbearing potential (non-childbearing potential is defined as post-menopause for at least one year or surgical sterilisation or hysterectomy at least three months before the study starts)
5. Use of adequate double contraception in women with childbearing potential [oral or injectable contraception or hormonal intra-uterine system (IUS) combined with condom]

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Participation in another clinical trial during the preceding 3 months
2. Pregnancy, lactation
3. Any acute medical disorder
4. History of relevant diseases of vital organs, of the central nervous system or other organs
5. Gastrointestinal disorders with uncertain absorption of orally administered drugs (e.g. partial or total gastrectomy, enterectomy, inflammatory bowel disease, celiac disease, symptomatic lactose intolerance, other disorders associated with chronic diarrhoea)
6. Subjects with a medical disorder, condition or history of such that would impair the subjects ability to participate or complete this study in the opinion of the investigator or the sponsor
7. Known hypersensitivity to lavender preparations
8. Regular daily consumption of more than 25 cigarettes
9. Regular daily consumption of more than half litre of usual beer or the equivalent quantity of approximately 20 g of alcohol in another form
10. Regular daily consumption of more than one litre of xanthin-containing beverages
11. Use of medication within the 2 weeks preceding the study which could interfere with the investigational product
12. Prohibited concomitant medication
13. Relevant deviation from the normal range in clinical chemistry, haematology or urinalysis
14. Resting heart rate in the awake subject below 45 beats per minute (BPM) or above 100 BPM
15. Systolic blood pressure below 90 mmHg for women and below 100 mmHg for men or above 150 mmHg
16. Diastolic blood pressure above 95 mmHg
17. History or evidence of alcohol and/or substance abuse or dependence, particularly of sedatives, hypnotics and anxiolytics within last 6 months before the study
18. Subjects testing positive in the drug screening
19. Participation in any previous clinical study with Silexan®/Lavender oil WS1265 or participation in a further clinical trial at the same time
20. Massive deviation from normal quantitativee electroencephalography (EEG) parameters

Date of first enrolment
28/02/2011

Date of final enrolment
30/10/2011

Locations

Countries of recruitment
Germany

Study participating centre
NeuroCode AG
Wetzlar
Germany
35578

Sponsor information

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

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration