

# 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

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| <b>Submission date</b><br>08/02/2011   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>18/03/2011 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>18/03/2011       | <b>Condition category</b><br>Mental and Behavioural Disorders | <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

Dr Winfried Wedekind

### Contact details

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Wetzlar  
Germany  
35578

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Study design**

Single-centre randomised double-blind placebo-controlled crossover 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 contact details below to request a patient information sheet

### **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 administration; 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 measure**

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

## **Secondary outcome measures**

No secondary outcome measures

## **Overall study start date**

28/02/2011

## **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

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

2 x 24 healthy volunteers (3 sequences, each with 8 subjects in both parts).

## 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 quantitative 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)

**Sponsor details**

Dr. Willmar Schwabe Strasse 4

Karlsruhe

Germany

76227

**Sponsor type**

Industry

**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