# Effects of Silexan on brain function and brain structure

Submission date Recruitment status Prospectively registered 12/07/2011 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 04/08/2011 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 25/02/2015 Nervous System Diseases

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Siegfried Kasper** 

#### Contact details

Währinger Gürtel 18-20 Vienna Austria 1090

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 750201.01.029

# Study information

Scientific Title

Effects of Silexan (WS® 1265) on the serotonin-1A (5-HT1A) receptor and microstructure of the brain: a randomized, placebo-controlled, double-blind, cross-over study with molecular and structural neuroimaging

# **Study objectives**

The objective of the study is to detect effects of an at least eight-week treatment with Silexan (WS® 1265) on the serotonergic system and the microstructure of the brain via molecular and structural neuroimaging.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Ethics Committee of the Medical University of Vienna (Ethik-Kommission des Medizinischen Universität Wien), 11/07/2011, ref: 475/2011

# Study design

Single-centre randomized placebo-controlled double-blind cross-over study

## Primary study design

Interventional

# Secondary study design

Randomised cross over trial

# Study setting(s)

Hospital

# Study type(s)

Other

## 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

Brain function

#### Interventions

- 1. The volunteers take 1  $\times$  2 capsules orally in the morning for eight weeks followed by a wash out phase without treatment of 2-3 weeks followed by a second treatment period of eight weeks
- 2. The randomized order of the two eight-weeks-periods is Silexan placebo or placebo Silexan
- 3. The dosage of a capsule with Silexan is 80 mg

# Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

## Primary outcome measure

1. Regional 5-HT1A receptor binding potential of the brain after at least 8 weeks of Silexan (WS® 1265) treatment as compared to placebo (positron emission tomography [PET] scan data) 2. Regional brain grey matter density and volume after at least 8 weeks of Silexan (WS®1265) treatment as compared to placebo (magnetic resonance imaging [MRI] scan data)

# Secondary outcome measures

- 1. Physical examination
- 2. Vital signs
- 3. Adverse events
- 4. Laboratory tests

## Overall study start date

01/08/2011

# Completion date

31/12/2012

# **Eligibility**

## Key inclusion criteria

- 1. Age 20 50 years
- 2. Male
- 3. Caucasian
- 4. Informed consent
- 4. Healthy
- 5. Body mass index between 18 and 29.9 kg/m<sup>2</sup>

# Participant type(s)

Healthy volunteer

## Age group

Adult

#### Lower age limit

18 Years

#### Sex

Male

# Target number of participants

18

#### Key exclusion criteria

- 1. Subjects with depression or comorbid axis I diagnoses
- 2. Subjects who are not naive to psychotropic drug treatment targeting the serotonergic system
- 3. Blood donation of approximately 500 ml within 3 months prior to the study start
- 4. A history of relevant diseases of vital organs, of the central nervous system or other organs

- 5. Subjects with a medical disorder, condition or history of such that would impair the subject's ability to participate or complete this study
- 6. Febrile illness within 1 week before the start of the study
- 7. Subjects with a history of severe allergies, non-allergic drug reactions, or multiple drug allergies
- 8. Regular daily consumption of more than  $\frac{1}{2}$  liter of regular beer or the equivalent quantity of approximately 20g of alcohol in another form
- 9. Regular daily consumption of more than 10 cigarettes
- 10. Regular use of therapeutic or recreational drugs
- 11. Subjects with known hypersensitivity to essential oils
- 12. Use of medication within the 2 weeks preceding the study which could interfere with the investigational product; chemistry
- 13. Resting heart rate in the awake subject below 45 BPM or above 90 BPM
- 14. Systolic blood pressure below 100 mmHg or above 140 mmHg
- 15. Diastolic blood pressure above 85 mmHg
- 16. Subjects testing positive in the drug screening

#### Date of first enrolment

01/08/2011

#### Date of final enrolment

31/12/2012

# Locations

#### Countries of recruitment

Austria

# Study participating centre Währinger Gürtel 18-20

Wanring Vienna Austria 1090

# Sponsor information

# Organisation

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

## Sponsor details

c/o Mr Stephan Klement 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

Willmar Schwabe GmbH and 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

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/10/2014		Yes	No