

Effects of Silexan on brain function and brain structure

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

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

Protocol serial number
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

Study type(s)

Other

Health condition(s) or problem(s) studied

Brain function

Interventions

1. The volunteers take 1 x 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)

Silexan (WS® 1265)

Primary outcome(s)

1. Regional 5-HT_{1A} 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)

Key secondary outcome(s))

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

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/m²

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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 ½ 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

Vienna

Austria

1090

Sponsor information

Organisation

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

ROR

<https://ror.org/043rrkc78>

Funder(s)

Funder type

Industry

Funder Name

Willmar Schwabe GmbH and Co KG (Germany)

Results and Publications

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