

# Effects of Silexan on brain function and brain structure

<b>Submission date</b> 12/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/02/2015	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## 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<sub>1A</sub> 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/m<sup>2</sup>

**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?
<a href="#">Results article</a>	results	31/10/2014		Yes	No