

# Efficacy of Silexan in anxious patients

<b>Submission date</b> 04/10/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2012	<b>Condition category</b> 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

Background and study aims:

Silexan is an essential oil produced from fresh *Lavandula angustifolia* flowers. The objective of the study is to show that Silexan is effective and safe in treating mixed anxiety and depression, where the main symptoms are low mood, prominent anxiety, loss of interest with associated symptoms, restlessness and tension and disturbed sleep.

Who can participate?

Adult male and female patients (aged 18-65 years) with symptoms of anxiety and depression.

What does the study involve?

One group of the patients will receive Silexan for 10 weeks. The other group will take a placebo (dummy) instead. During the study the severity of the symptoms of the disease will be measured using established scales. The scales are either self-reported or will be assessed by a trained assessor.

What are the possible benefits and risks of participating?

The participants who receive verum can expect an improvement of their symptoms of anxiety and depression. There are no known risks of using lavender oil active ingredients.

Where is the study run from?

From about 30 medical centres in Germany.

When is the study starting and how long is it expected to run for?

The study will start in October 2012 and will run for about 15 months until the required number of 300 patients have been recruited and treated.

Who is funding the study?

Dr. Willmar Schwabe GmbH & Co. KG, Germany

Who is the main contact?

Dr. Stephan Klement

Stephan.klement@schwabe.de

## Contact information

Type(s)

Scientific

**Contact name**

Prof Hans-Peter Volz

**Contact details**

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Germany  
97444

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

750201.01.035

## **Study information**

**Scientific Title**

Multi-center, double-blind, placebo-controlled, randomized phase III study to prove the efficacy, safety and tolerability of Silexan (WS®1265) in patients with mixed anxiety and depressive disorder

**Study objectives**

The objective of the study is to prove the efficacy of Silexan (WS®1265) in the treatment of patients with mixed anxiety and depressive disorder in comparing the change of the HAMA total score and the MADRS total score between baseline and Week 10 between Silexan and placebo.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethik-Kommission bei der Medizinischen Fakultät der Universität Würzburg, 14 September 2012  
ref: 180/12\_ff

**Study design**

Multi-center double-blind placebo-controlled randomized phase IIIb 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 the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Mixed anxiety and depressive disorder

**Interventions**

80 mg/day Silexan or placebo for 70 days

**Intervention Type**

Other

**Phase**

Phase III

**Primary outcome measure**

The change of the HAMA total score and the MADRS total score

**Secondary outcome measures**

1. Response criteria (50 % reduction; remission) based on the HAMA total score and on the MADRS total score
2. Items 2 (tension) and 14 (behaviour at interview) of the HAMA, change and response
3. Single items and subscores of the Hamilton Rating Scale for Anxiety
4. Single items of the MADRS
5. State-Trait Anxiety Inventory (STAI)
6. Total score, subscores state anxiety and trait anxiety, early improvement on day 3
7. Subscales of the Sheehan Disability Scale (SDS) and subscores of the SF-36
8. Clinical Global Impressions
9. Hospital Anxiety and Depression Scale (HADS), total score change, subscore depression and subscore anxiety

**Overall study start date**

29/10/2012

**Completion date**

31/12/2013

**Eligibility****Key inclusion criteria**

1. Diagnosis of mixed anxiety and depressive disorder (ICD-10, F41.2)
2. Age 18 to 65 years

3. HAMA total score  $\geq 18$  with item 1 anxious mood  $\geq 2$  (moderate) and item 6 depressed mood  $\geq 2$  (moderate)
4. BMI between 18 and 29.9 kg/m<sup>2</sup>
5. Written informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

300

**Key exclusion criteria**

1. Any clinically important psychiatric or neurological diagnoses, other than study indication, within 6 month before the study
2. Risk of suicide (MADRS item 10  $\geq 2$  during study) or previous suicide attempt or clear display of auto-aggressive behaviour
3. History or evidence of alcohol and/or substance abuse or dependence
4. Current use of other psychotropic drugs within 30 days before baseline visit
5. History of hypersensitivity to Lavender preparations
6. Any unstable acute medical disorder
7. Unacceptability to discontinue or likelihood to need medication during the study that is prohibited as concomitant treatment
8. Non-medical psychiatric treatment during the course of the study
9. Clinical significant abnormality of ECG and/or laboratory values
10. Pregnancy, lactation

**Date of first enrolment**

29/10/2012

**Date of final enrolment**

31/12/2013

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Bezirk Unterfranken

Werneck

Germany  
97444

## Sponsor information

### Organisation

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

### Sponsor details

Willmar-Schwabe-Straße 4  
Karlsruhe  
Germany  
76227

### Sponsor type

Industry

### Website

<http://www.schwabepharma.com/>

### ROR

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

## Funder(s)

### Funder type

Industry

### Funder Name

Dr. Willmar Schwabe GmbH & Co. (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