ISRCTN65844716 https://doi.org/10.1186/ISRCTN65844716

Efficacy of Silexan in anxious patients

Submission date	Recruitment status	[X] Prospectively registered
04/10/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/10/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/10/2012	Mental and Behavioural Disorders	[ ] 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 know 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
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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
The change of the HAMA total score and the MADRS total score

Key secondary outcome(s))
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

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 ≥ 18 with item 1 anxious mood ≥ 2 (moderate) and item 6 depressed mood ≥ 2 (moderate)
4. BMI between 18 and 29.9 kg/m2
5. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 ≥ 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)

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type

Industry

Funder Name
Dr. Willmar Schwabe GmbH & Co. (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration