

Phase III study to prove the efficacy, safety and tolerability of Silexan® in patients with anxiety disorder

Submission date 04/08/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2008	Overall study status Completed	☐ Protocol
Last Edited 12/09/2008	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Angelika Dienel

Contact details
Willmra-Schwabe-Strasse 4
Karlsruhe
Germany
76227

Additional identifiers

Protocol serial number
750201.01.013

Study information

Scientific Title

Study objectives

To prove the efficacy of Silexan® (a lavender oil preparation) in patients suffering from an anxiety disorder not otherwise specified (NOS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the State Medical Chamber of Baden-Württemberg (Landesärztekammer Baden-Württemberg). Date of approval: 15/06/2004 (ref: 093-04)

Study design

Phase III, multi-centre, double-blind, randomised, placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anxiety disorder not otherwise specified

Interventions

Silexan® 80 mg (1 capsule) per day or placebo orally for 10 weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Silexan®

Primary outcome(s)

1. Change in HAMA total score, assessed every 2 weeks for 10 weeks
2. Change in PSQI total score, assessed at baseline and Week 2, 6 and 10

Key secondary outcome(s)

1. Subscores of HAMA, assessed every 2 weeks for 10 weeks
2. Subscores of PSQI, assessed at baseline and Week 2, 6 and 10
3. Clinical Global Impressions (CGI) scale at baseline, Week 8 and 10
4. Zung's Self-rating Anxiety Scale, assessed every 2 weeks for 10 weeks
5. Short-Form 36 (SF-36) Health Survey Questionnaire at baseline and Week 10
6. Safety, assessed every 2 weeks for 10 weeks. After this period, adverse events were monitored until they had subsided or had stabilised.

Completion date

04/04/2005

Eligibility

Key inclusion criteria

1. Age range: 18 - 65, both males and females
2. Primary diagnosis of an anxiety disorder NOS according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV; 300.00)
3. Severity of anxiety for the inclusion: the Hamilton Anxiety Scale (HAM-A) total score ≥ 18 , Item 1 "anxious mood" ≥ 2 , Item 2 "insomnia" ≥ 2
4. Severity of sleep disorders for the inclusion: Pittsburgh Sleep Quality Index (PSQI) total score > 5

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. A decrease of 25% or more of the HAM-A total score during the screening phase
2. Any clinically important psychiatric or neurological diagnoses other than an anxiety disorder NOS within 6 month before the study
3. Risk of suicide
4. History or evidence of alcohol and/or substance abuse or dependence
5. Current use of other psychotropic drugs
6. Any unstable acute medical disorder
7. Prohibited concomitant treatment: any psychotropic drugs including benzodiazepines, non-benzodiazepines (zopiclone, zolpidem), neuroleptics, tranquiliser, antidepressives, antiepileptics, antihistaminics
8. Long-term prophylactic treatment
9. Central-acting antihypertensive medication
10. Anti-Parkinson's medication
11. Phyto-anxiolytics
12. Muscle relaxants
13. Analgetics of opiate type
14. Anaesthetics
15. Barbiturates
16. Nootropics
17. Non-medical psychiatric treatment

Date of first enrolment

16/09/2004

Date of final enrolment

04/04/2005

Locations

Countries of recruitment

Germany

Study participating centre

Willmra-Schwabe-Strasse 4

Karlsruhe

Germany

76227

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. KG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration