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

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

Kev 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