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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
16/09/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
220

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)

Sponsor details
Willmar-Schwabe-Strasse 4
Karlsruhe
Germany
76227

Sponsor type
Industry

ROR

https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr. Willmar Schwabe GmbH & Co. KG (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