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A televised, web-based randomised trial of an herbal remedy (valerian) for insomnia

Submission date	Recruitment status	[_] Prospectively registered
22/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2007	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2005001TVT

Study information

Scientific Title

Acronym

SøvnStudien

Study objectives
The primary objective is to evaluate whether valerian root (valerian) improves the self-assessed quality of sleep compared with placebo for people with primary insomnia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Committee for Medical Research Ethics for Southern Norway (Regional komité for medisinsk forskningsetikk, Sør- Norge) 5 January 2006, Ref: S-05280

Study design
Randomised, double-blind, parallel group, placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary insomnia

Interventions
Coated Valerian Forte tablets 200 mg extract per tablet, corresponding to 1200 mg Valeriana officinalis. 3 tablets to be taken every night for 14 days

Information about the study will be televised nationally on a weekly health program. Viewers interested in participation will be invited to visit the web pages of the study to enrol. Participant registration and data collection will be by use of Internet.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Proportion of participants in each group with an improvement in self-assessed quality of sleep of > or = 0.5 units between the average score for the 2 weeks before and 2 weeks during treatment

Key secondary outcome(s))
1. Proportion of participants in each group with an improvement of > or = 0.5 units between the average score for the 2 weeks before and 2 weeks during treatment for each of the four variables:
1.1 Sleep latency

1.2 Number of awakenings
1.3 Total sleep time
1.4 Energy level during the day

2. Mean changes in the five outcomes listed above

3. Global self-assessment

If a difference is not found between the treatment groups for the primary and secondary variables, the following explorative variables will be analysed:
1. Proportion of participants in each group with any improvement in mean difference (i.e. all score changes > 0) between the average score for the 2 weeks before and 2 weeks during treatment for each of the five variables:
1.1 Quality of sleep
1.2 Sleep latency
1.3 Number of awakenings
1.4 Total sleep time
1.5 Energy level during the day

2. Difference in the profile of the five endpoints during the intervention period taking into account the baseline period, including a potential time effect

Completion date
30/03/2007

Eligibility

Key inclusion criteria
1. Aged 18 75 years, both inclusive
2. Insomnia lasting more than one month
3. Pittsburgh Sleep Quality Index (PSQI) score of > 5
4. Provide name of primary physician
5. Access to internet and own email address
6. At least 10 days of the sleep diary completed prior to randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria

1. Secondary insomnia
2. Use of hypnotics by prescription
3. Depression
4. Alcohol or drug abuse
5. Psychotherapy within the past six months
6. Sleep apnoea, periodic limb movements disorder or restless legs syndrome
7. Pregnant or lactating women or women of childbearing potential who do not use an approved method of contraception (oral contraceptives orIntrauterine device [IUD])
8. Shift workers
9. History of hypersensitivity to valerian or its constituents
10. Participant rating of usually or always to the following questions in the Global Sleep Assessment Questionnaire:
During the past four weeks, how often:
a. Did you hold your breath, have breathing pauses, or stop breathing in your sleep?
b. Did you have restless or "crawling" feelings in your legs at night that went away if you moved your legs?
c. Did you have repeated rhythmic leg jerks or leg twitches during your sleep?
d. Did you have nightmares, or did you scream, walk, punch, or kick in your sleep?
e. Did any of the following disturb you in your sleep:
f. Pain?
g. Other physical symptoms?
h. Medications?
i. Did you snore loudly?
11. Current participation in another trial using an investigational compound

Date of first enrolment
29/01/2007

Date of final enrolment
30/03/2007

Locations

Countries of recruitment
Norway

Study participating centre
Norwegian Knowledge Centre for the Health Services
Oslo
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N-0130

Sponsor information

Organisation
Norwegian Knowledge Centre for the Health Services (Norway)

ROR
https://ror.org/01thff661

Funder(s)

Funder type
Government

Funder Name
Norwegian Knowledge Centre for the Health Services (Norway)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	17/10/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes