

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 22/01/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 01/03/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 25/10/2007 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Study website

<http://sovnstudien.forskningspuls.no/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

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

Overall study start date

29/01/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

500 to 550

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 or Intrauterine 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

Norway

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Sponsor information

Organisation

Norwegian Knowledge Centre for the Health Services (Norway)

Sponsor details

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Sponsor type

Government

Website

<http://www.kunnskapssenteret.no>

ROR

<https://ror.org/01thff661>

Funder(s)

Funder type

Government

Funder Name

Norwegian Knowledge Centre for the Health Services (Norway)

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

Study outputs

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