Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388

Protocol summary

Summary

The objective of the study is to assess the effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388. More than 250 volunteered menopausal women will be interviewed using Pittsburg Sleep Quality Index Questionnaire (PSQI). About 100 of those who scored 5 or more will be invited to participate in the study and fill in a written consent form. Major inclusion and exclusion criteria include: • Not having physical and psychological diseases which may cause sleep problems • Not to use tobacco, drugs and alcohol • Appearance of any physical illness and psychological disorder while in study • Significant change in sleep conditions such as travel, shift work, etc. • Taking any additional medication during the study • Not taking the drug under investigation for more than 7 days during the study. Subjects will be randomly divided into two 50 intervention and control groups. The intervention group will receive Sedamin, 530 mg capsule, twice daily for one month and the control group will receive placebo capsule, at the same dose as the intervention group. Pittsburg Sleep Quality Index questionnaire score will be measured and compared in the two groups before and one month after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903252172N4**
Registration date: **2010-06-29, 1389/04/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-06-29, 1389/04/08

Registrant information

Name

Simin Taavoni

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388

Public title

Effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion and Exclusion criteria: • Not having physical and psychological diseases which may cause sleep problems • Not to use tobacco, drugs and alcohol • Appearance of any physical illness and psychological disorder while in study • Significant change in sleep conditions such as travel, shift work, etc. • Taking any additional medication during the study • Not taking the drug under investigation for more than 7 days during the study
Age
From **50 years** old to **60 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Nursing and Midwifery Faculty, Iran University of Medical Sciences
Street address
Valiasr street, after mirdamad,rashid yasemi street
City
Tehran
Postal code
19395/4798
Approval date
2010-03-12, 1388/12/21
Ethics committee reference number
1603057

Health conditions studied

1

Description of health condition studied
Sleep disorders
ICD-10 code
F51.0, F51
ICD-10 code description
Nonorganic sleep disorders

Primary outcomes

1

Description
Sleep dysfunction score
Timepoint
Before intervention and one month after intervention
Method of measurement
Pittsburg Sleep Quality Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group, Sedamin, 530 mg capsule, twice daily for one month
Category
Treatment - Drugs

2

Description
Control group, Starch, placebo capsule, twice daily for one month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeyni health center
Full name of responsible person
Shiva Eshtehardi, midwife
Street address
Saat Square, Old Karaj Road, Ghods City (Ghaleh Hassan Khan)
City
Ghods

2

Recruitment center
Name of recruitment center
Emam Hoseyn health center

Full name of responsible person
Zahra Eskandarizade, MD, manager
Street address
Shahid Alami street, Azadi Square, Old Karaj Road, Ghods City (Ghaleh Hassan Khan)
City
Ghods

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for reasearch, Iran University of Medical Sciences
Full name of responsible person
Dr. Saeid Abass Motevalain, Dr. Mazyar Moradie Lakea
Street address
Vanak Highway, Next to Milad Hospital
City
Tehran
Grant name
Grant code / Reference number
854 کد
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for reasearch, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Nursing and Midwifery Faculty, Iran University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty