

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Iran (Islamic Republic of)

Phone

+98 21 8820 8161

Email address

staavoni@iums.ac.ir

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 addressShahid Alami street, Azadi Square, Old Karaj Road,
Ghods City (Ghaleh Hassan Khan)**City**

Ghods

1919915375

Phone

00982182471000; 00982182471111

Fax**Email**

staavoni@iums.ac.ir; staavoni14@yahoo.com

Web page address**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 sourceVice 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**Full name of responsible person**

Simin Taavoni

PositionM.Sc in Medical Education, M.Sc in Midwifery
Education, Academic Faculty Member & Resaercher**Other areas of specialty/work****Street address**3rd Floor, No.12, Nadjmabady St. Kazeroon St.
Mirdamad Ave**City**

Tehran

Postal code**Person responsible for scientific inquiries****Contact****Name of organization / entity**Nursing and Midwifery Faculty, Iran University of
Medical Sciences**Full name of responsible person**

Simin Taavoni

PositionM.Sc in Medical Education, M.Sc in Midwifery
Education, Academic Faculty Member & Resaercher**Other areas of specialty/work****Street address**3rd Floor, No.12, Nadjmabady St. Kazeroon St.
Mirdamad Ave.**City**

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1919915375

Phone

00982182471000; 00982182471111

Fax**Email**

staavoni14@yahoo.com; staavoni@iums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**Nursing and Midwifery Faculty, Iran University of
Medical Sciences**Full name of responsible person**

Simin Taavoni

PositionM.Sc in Medical Education, M.Sc in Midwifery
Education, Faculty Member & Researcher**Other areas of specialty/work****Street address**3rd Floor, No.12, Nadjmabady St. Kazeroon St.
Mirdamad Ave. zip code: 1919915375**City**

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staavoni14@yahoo.com; staavoni@iums.ac.ir

Web page address

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