

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation the effect of valerian on sleep quality, insomnia severity, anxiety and hotflash in menopause women

Protocol summary

Summary

The purpose of this study is to compare the effect of valerian on sleep quality, insomnia severity, anxiety and Hot flashes in postmenopausal women. This study is a randomized clinical trial among 142 postmenopausal women referred to clinics of Tehran University of Medical Sciences, which have sleep disorder and Hot flashes. The women were randomly divided into two groups. Each group received either 700 mg of valerian extract or a placebo (two 350 mg capsules an hour before bedtime) for 4 weeks. After wash out period (two weeks) the intervention and control groups are moved together again. After one month will be reviewed sleep quality, insomnia severity, anxiety and hot flashes in two groups. Anxiety levels sleep quality, insomnia severity and hot flashes were measured before and after intervention. Symptoms between two groups are compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102275912N3**

Registration date: **2012-07-07, 1391/04/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-07, 1391/04/17

Registrant information

Name

Mandana Mir Mohammad Ali Ei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

mirmohammad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences (TUMS)

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-09-19, 1391/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of valerian on sleep quality, insomnia severity, anxiety and hotflash in menopause women

Public title

Evaluation the effect of Valerian on sleep quality, insomnia severity, anxiety and hot flash in menopause women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Their age is between 60-45 years ; They have passed at least one year of amenorrhea ; Have a sleep disorder. More Pystbrg index equal to 5 ; not using Of drugs, tranquilizers, sleeping hormone replacement ; Do not have chronic systemic disease known to affect sleep ; Do not have mental illness ; have not consume Tobacco (cigarettes and shisha) and alcohol ; During a recent divorce, serious illness or death of

family members is not really happening ; According to the research units having hot flashes Exclusion criteria: If the samples during the study of drugs, tranquilizers, sleeping or using hormone replacement ; If during the study divorce, serious illness or death of family members happened to be ; The use of tobacco (cigarettes or shisha) volatile during the research ; Irregular use of Valerian

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

6th Floor., University of Central Organization, Ghods St,Keshavarz Blvd

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

1298/130/5

Health conditions studied

1

Description of health condition studied

Menopausal and other perimenopausal disorders

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

sleep quality

Timepoint

Before intervention, one month after the intervention,
One month after the second intervention

Method of measurement

Questionnaire

2

Description

hotflash

Timepoint

Before intervention, one month after the intervention,
One month after the second intervention

Method of measurement

VAS

3

Description

insomnia severity

Timepoint

Before intervention, one month after the intervention,
One month after the second intervention

Method of measurement

Questionnaire

4

Description

anxiety

Timepoint

Before intervention, one month after the intervention,
One month after the second intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

side effect of drug

Timepoint

Beginning of the study , after 1 month , end of the study

Method of measurement

by questionnaire Pittsburgh Sleep Quality Index

Intervention groups

1

Description

Valerian 700 mg daily (two capsules 350 mg) one hour before bedtime for a period of 1 month

Category

Treatment - Drugs

2**Description**

placebo 700 mg daily (two capsules 350 mg starch) one hour before bedtime for a period of 1 month

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farmanfarmaeyan clinic

Full name of responsible person

Tahere Zendedel

Street address

In front of Bank Melli Iran,Before Roshdiye cross,Azarbayegan st.

City

Tehran

2**Recruitment center****Name of recruitment center**

Meisam clinic

Full name of responsible person

Tahere Zendedel

Street address

Near meysam center,Obid zakani st,Ghapan Crossroads,Ghazvin st

City

tehran

3**Recruitment center****Name of recruitment center**

Shaheed Vahedi clinic

Full name of responsible person

Tahere Zendedel

Street address

Near the Women's Organization,Amozegar st,Yakhchi abad

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Fotouhi vice chancellor for research- Tehran University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Nosrat ST,Tohid Sq.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Tahereh Zendedel

Position

MS student

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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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