Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Scinces

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 ; Iregular 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/د

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
Nosrat st. Toheid sq. Nursing &midwifery faculty
City
Tehran
Postal code
Phone
+98 21 61054
Fax
Email
mirmohamad1@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences (TUMS)
Full name of responsible person
Mandana Mirmohamad aliei
Position
Instructor /MS
Other areas of specialty/work
Street address
Nosrat ST,Tohid Sq, Faculty of Nursing and Midwifery
City
Tehran
Postal code
Phone

+98 21 61054

Fax

Email

irmohamad1@yahoo.com

Web page address

Person responsible for updating data

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

Nosrat st. Toheid sq. Nursing &midwifery faculty

City

Tehran

Postal code

Phone

+98 21 6154

Fax

Email

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