Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of red clover and passion flower capsules on sleep disorder among menopausal women

Protocol summary

Summary

This study is a clinical trial designed to determine the effect of Passion flower and red clover oral capsules on sleep disorders in women aged 50-60. 120 healthy postmenopausal volunteers referred to Abuzar clinic and Women Hospital (40 persons in each group) eligible for entry (inclusion criteria: cessation of menstruation for at least 12 months due to menopause, any history of consuming alcoholic drink, smoking, addiction or any kind of hormonal drugs.) were enrolled into the study after completing the informed consent. Exclusion criteria were any kind of physical or mental disease that appears during the study and causes sleep disorders, significant change in conditions of sleep such as traveling, anything that causes sleep disturbance during the study. The subjects include three groups: treated with passion flower, red clover and the control group. The treatment group received 2 gr passion flower (plant leaves), or 40 mg red clover, or 40 mg starch (controls) (capsules of the same form twice a day for eight weeks). The tools of study consisted of demographic questionnaire and Pittsburgh sleep Index questionnaire recorded and compared before treatment and eight weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407092172N18**
Registration date: **2014-08-09, 1393/05/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-09, 1393/05/18

Registrant information

Name
Simin Taavoni
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of red clover and passion flower capsules on sleep disorder among menopausal women

Public title

Effect of red clover and passion flower capsules on sleep disorder among menopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women volunteers without known disease who passed through natural menopause; No history of consuming alcoholic drink, smoking, addiction or any kind of hormonal drugs. Exclusion criteria: any

kind of physical or mental disease that appear during the study and causes sleeping disorders; A significant change in influential conditions on sleeping unpredictable such as traveling changing the location; Any incident during the study to make the patient sleepless.

Age
From **50 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
No 23, Dameshgh St., Valiasr Ave

City
Tehran

Postal code

Approval date
2014-06-18, 1393/03/28

Ethics committee reference number
92-02-28-23388-101905

Health conditions studied

1

Description of health condition studied
Sleep disorders

ICD-10 code
G47.0

ICD-10 code description
Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description
Score of sleeping disorder

Timepoint
Before intervention, 2monthes after intervention

Method of measurement
Pittsburgh sleeping disorder questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1:Oral consumption of passion flower, 2gr capsule, twice a day for 2 month

Category
Treatment - Drugs

2

Description
Placebo Group: Capsule 40 mg containe starch, twice a day, for 2monthes

Category
Placebo

3

Description
Intervention 1:Oral consumption of red clover, 40 mg capsule, twice a day for 2 month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Menopause Clinic of OB&GYN hospital: Jame Zanan Hospital

Full name of responsible person
Mojgan Asadi

Street address
Jame Zanan Hospital of Tehran,Above of Zamin shahri Organization, North Nejatollahi Ave, Karim Khan Zand Ave.

City
Tehran

2

Recruitment center

Name of recruitment center

Abuzar Clinic

Full name of responsible person

Maryam Maleki

Street address

Adjacent to the sports center, Abuzar square, District 17

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Esmat Karimi

Street address

No 23, Dameshgh St., Valiasr Ave

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, 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

Nursing and Midwifery Faculty, Tehran University of Medical Sciences

Full name of responsible person

Simin Taavoni

Position

M.Sc in Medical Education, M.Sc in Midfwifery Education, Faculty Member & Resaercher

Other areas of specialty/work

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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