

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 8161

Email address

staavoni@iums.ac.ir

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

+98 21 8820 8161

Fax

Email

staavoni14@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nursing and Midwifery Faculty, Tehran University of Medical Sciences

Full name of responsible person

Simin Taavoni

Position

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Other areas of specialty/work

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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

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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