

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of oral red clover drug on the severity of menopausal symptoms of 50-59 years old women attendant to menopausal clinic.

Protocol summary

Summary

The randomized control clinical trial will be conducted to assess the effect of red clover on the severity of menopausal symptoms. Inclusion Criteria: Naturally menopausal women with 50-59 years old; Negative history of physical and psychological disease; Negative history of hormone therapy and herbal medicine; Stop using red clover and placebo for 1 month; Allergy to red clover.

Following approval of the proposed study design, the study sample of 110 women, who had entered the menopausal period naturally and referred to Tehran university clinics, will be assigned randomly into two groups, the test group who will receive two capsules of red clover per day for 90 days, or the control group who will receive the equal design of placebo capsules. Formal consent will be taken from all participants at the beginning. The outcome measures include menopausal symptoms, as obtained through the Menopause Rating Scale. Four MRS scores will be obtained through the study for every participant (before intervention and during the first, second, third month of intervention) and the severity of menopausal symptoms will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112172172N13**

Registration date: **2012-02-02, 1390/11/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-02, 1390/11/13

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

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral red clover drug on the severity of menopausal symptoms of 50-59 years old women attendant to menopausal clinic.

Public title

Effect of Red Clover on menopausal symptoms.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : naturally menopausal women, 50-59 years old; Negative history of cancer; Negative history of

physical and psychological disease; Negative history of hormone therapy and herbal medicine; Negative history of allergy to Red Clover, Soy bean and other herbal medicine. Exclusion criteria: Under medication by hormone therapy, antibiotic or anti acid (due to inhibition of herbal medicine absorption); Starting any type of herbal medication more than once a week during the study; Starting vegetarian diet during the study; allergy to Red Clover during the intervention; Poor cooperation during the study Stop using Red Clover/placebo for 6 day in 1 month; Obese women with BMI>38kg/m2

Age

From **50 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

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 Department

Street address

No 23, Dameshgh St., Valiasr Ave

City

Tehran

Postal code

Approval date

2011-12-18, 1390/09/27

Ethics committee reference number

15265

Health conditions studied

1

Description of health condition studied

Menopausal symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Severity of Menopausal symptoms scores

Timepoint

Before intervention, at the end of first, second and third of intervention after intervention

Method of measurement

Menopausal Rating Scale

Secondary outcomes

1

Description

Severity of physical symptom scores.

Timepoint

Before intervention, at the end of first, second and third of intervention after intervention

Method of measurement

Menopausal Rating Scale

2

Description

Severity psychological symptom score

Timepoint

Before the intervention, at the end of first, second and third of intervention

Method of measurement

Menopause Rating Scale

3

Description

Severity of urogenital symptom score

Timepoint

Before the intervention, at the end of first, second and third of intervention

Method of measurement

Menopause Rating Scale

Intervention groups

1

Description

Intervention 1: Oral administration 40 mg Red clover capsule, twice a day for 3 months

Category

Treatment - Drugs

2

Description

Placebo Group: Capsule 50 mg containing starch, twice a

day,for 3 monthes

Category

Placebo

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

Menopause Clinic of OB&GYN hospital: Jame Zanan Hospital & Abuzar clinic

Full name of responsible person**Street address****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 Karimie

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 Midwifery Education, Faculty Member & Researcher

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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