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 yeares old women attendant to menopausal clinic.

Protocol summary

Summary

The randomized control clinical trial will conducted to assess the effect of red clover on severity 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 days in 1 month; Allergy to red clover. Following approval of 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, test group who will receive two capsules of red clover per day for 90 day period, or the control group who will receive the equal design of placebo capsules. Formal contest will be taken from all participants at beginning. The output measures include menopausal symptoms, as obtain through the Menopause Rating Scale. Four MRS score will be obtained through the study for every participants (before intervention and during the first, second third month of intervention) and the severity of menopausal symptom 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

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Simin Taavoni
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Iran University of Medical Sciences
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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 yeares 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 symptome 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 urogental 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 clovercapsule, twice a day for 3 month

Category
Treatment - Drugs

2

Description
Placebo Group: Capsule 50 mg containe 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

Other areas of specialty/work

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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