Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effects of red clover on some of menopausal symptoms and quality of life in post-menopausal women under coverage of Isfahan’s selected health care center in 2010

Protocol summary

Summary

Objective: Considering that red clover is the rich source of phytoestrogens, this clinical randomized, triple-blind, placebo-controlled trial investigated the effect of red clover on quality of life in post-menopausal women. Methods: The menopausal women, who already have been under the coverage of this center and had inclusion criteria, included the study samples. Age>45 years, Amenorrhea>12 month and<5 year duration, Kupperman Index Score□15, Good general health. Able to give informed consent (Able to read and write) were main inclusion criteria and Having hormone therapy contraindications, Use of drugs that influence vasomotors symptoms, Occurrence of any serious event in the 6 months prior the study, taking the drugs that might reduce absorption of isoflavones, Consuming less than %80 of the expected capsules during one month were main non-inclusion criteria and exclusion. Seventy-two menopausal women were the study samples and after two weeks of monitoring, were randomized blindly to receive daily oral consumption one 45 mg red clover capsule or starch powder as placebo each morning with the breakfast meal for 8 weeks continued from end of the second week to end of the tenth week. The main outcomes were the menopausal symptoms and quality of life. Key Words: menopausal symptoms, phytoestrogens, quality of life, red clover.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902263936N1**
Registration date: **2012-01-08, 1390/10/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-08, 1390/10/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of red clover on some of menopausal symptoms and quality of life in post-menopausal women under coverage of Isfahan’s selected health care center in 2010

Public title

The effect of red clover on menopausal symptoms

Purpose
Treatment
Inclusion/Exclusion criteria
Main Inclusion criteria: Age>45 years, Amenorrhea>12 month and<5 year duration, Kupperman Index Score□15, Good general health. Able to give informed consent (Able to read and write). Main non-inclusion criteria and exclusion: Having hormone therapy contraindications, Use of drugs that influence vasomotors symptoms, Occurrence of any serious event in the 6 months prior the study, taking the drugs that might reduce absorption of isoflavones, Consuming less than %80 of the expected capsules during one month.
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Other Inclusion criteria: No use of treatments such as hormone therapy, dietary supplementations, herbal therapy in the six months prior to enrollment for relieving menopause symptoms, Interest in participation in the study. Other non-inclusion criteria and exclusion: The incidence of menopause at the ages under 40 years, Current treatment or therapy in the last 3 months with any of the following drugs: anticonvulsants, antidepressants, phenothiazines, benzodiazepines, ergot derivatives, □-blockers, central acting antihypertensive drugs,Vegetarian, Current participation in any other clinical trial, Disorder in the metabolism or sensitivity to estrogen or phytoestrogens (this criterion was assessed with asking the questions about record of using OCPs and incidence of any problem following the consumption of these pills).BMI□ 25kg/ m2, having any type of disease, Unwillingness to continue participation in the study, Occurrence of any serious event especially one that could affects the quality of life during the study, Occurrence of any potential complication during the study that could affect the subject's health. The data were collected in four phases: at the beginning of the study, at the end of the second, sixth and tenth weeks of study. Before the treatment and at the end of the study, menopause specific quality of life questionnaire (MENQOL) was completed in the two groups. Furthermore, menopausal symptoms weekly were recorded using KMI by the study subjects. The subjects were asked to bring the container at the final visit and thus the number of the remained capsules could be counted by one of the health care center's staff who was not informed about the study process. The study subjects were explained to avoid supplements containing soy more than once a week. During the medication consumption, which continued from end of the second week to end of the tenth week, the study subjects recorded their symptoms and were phone called weekly and regular drug consumption was reminded to them. Besides, phone number of the researcher also was given to the study subjects to contact the researcher.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences- hezargerib st-isfahan -I.R.IRAN
City
Isfahan
Postal code
Approval date
2010-05-10, 1389/02/20
Ethics committee reference number
389039

Health conditions studied

1

Description of health condition studied
Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climacteric

Primary outcomes

1

Description
Menopausal symptoms
Timepoint
Before the intervention (treatment), 4 and 8 weeks after beginning the intervention
Method of measurement
Kupperman menopausal index

2

Description

Quality of life

Timepoint

Before the intervention (treatment) and 8 weeks after beginning the intervention

Method of measurement

Menopause -specific quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Daily oral consumption one 45 mg red clover capsule each morning with the breakfast meal for 8 weeks continued from end of the second week to end of the tenth week.

Category

Treatment - Drugs

2

Description

In the control group: Daily oral consumption one 45 mg starch powder capsule each morning with the breakfast meal for 8 weeks continued from end of the second week to end of the tenth week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Navab Safavi Health Care Center affiliated to Isfahan University of Medical Sciences.

Full name of responsible person

kobra salehi

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences.

Full name of responsible person

Vice chancellor for research, Isfahan University of Medical Sciences.

Street address

Hazar garib avenue

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences.

Full name of responsible person

Kobra Salehi

Position

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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