Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Cornus mas fruit on menopausal symptoms in menopausal women

Protocol summary

Summary

Objectives: The aim of this double-blind Randomized Controlled Trial study is the effects of cornus mas fruit on menopausal symptoms. Inclusion and exclusion criteria: menopause women with at least one year after amenorrhea history; that suffer of menopausal symptoms. They shouldn't: have history of malignancies, have active hepatic or renal disease, take HRT or other menopausal treatments, take progesterone and consumption of cornus mas. Study population and sample size: 84 menopause women referred to Rassol Akram hospital in Tehran. Intervention: In ten days before the intervention, we will complete a Kuperman Index questionnaire and another questionnaire included demographic characteristics, gynecological history, frequency and duration of hot flashing. Also the blood samples are taken for hormone measurements. Samples will be divided randomly in two groups; intervention group will take 3 capsules containing 500 mg cornus mas and the placebo control group will take capsules containing 500 mg starch both for 10 days and the process will repeated for third, fourth and fifth days study. These two capsules will be coded, and pot in to similar boxes with using order inside them, then one of our coworkers who don't know about coding process will give capsules to samples. The number of hot flashes and Kuperman index will be completed again for both groups. Two groups will be compared and results will be analyzed by SPSS software. Primary outcomes: treatment of menopausal symptoms. Before the study, we will explain our study to participations, if they be agree and sign the letter of satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012070210166N1**

Registration date: **2012-07-13, 1391/04/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-13, 1391/04/23

Registrant information

Name

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Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Cornus mas fruit on menopausal symptoms in menopausal women

Public title

Effect of Cornus mas fruit on menopausal symptoms in menopausal women refers to the Clinics of Rasool Akram Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for intervention: Age 60-45 years; Amenorrhea for at least 12 months; Having at least 3 times in hot flushing medium during 24 hours and at least 2 weeks before study; Lack of history of allergy to Cornus mas use and its products; Not receiving hormone replacement therapy within 6 months; At present not use of estrogen and Medroxyprogestrone; Lack of effective drugs on hot flashes, such as clonidine, methyldopa, , veralpereid, naloxone and Tibolone; Lack of vaginal bleeding of unknown origin; Have not active liver disease and renal failure; No history of malignancy; No history of thromboembolism; Willingness to participate in the study. Exclusion criteria of intervention: Vegetarian diet; Soya consumption; Cornus mas consumption; Regular use of vitamin; Smoking; take antibiotics ; Unwillingness to continue Cornus mas consumption.

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: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences,Tehran, Hemmat Highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-02-07, 1393/11/18

Ethics committee reference number

93-03-27-24790

Health conditions studied

1

Description of health condition studied

menopausal symptoms

ICD-10 code

099-094

ICD-10 code description

Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description

Menopausal symptoms, some inflammatory and bone markers, body fat percent

Timepoint

Ten days before the intervention- Beginning of the second ten days of study- For ten days in the third and fourth and fifth of the study

Method of measurement

Kupperman menopausal index, Bio-Chemical testing, Bioelectrical Impedance Analysis

Secondary outcomes

1

Description

Abdominal pain، diarrhea

Timepoint

Once every ten days

Method of measurement

By interview

Intervention groups

1

Description

The intervention group will receive daily 3 capsules containing 500 mg of powdered Cornus mas for 4 weeks. Placebo group will receive daily 3 capsules containing 500 mg starch powder for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Rassol Akram hospital

Full name of responsible person
Shahla Chaichian
Street address
Rassol Akram hospital, Niaesh St, Sattar Khan St, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Dr. Mousavi
Street address
Iran University of Medical Sciences, Hemmat highway
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, Iran 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

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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