

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2026

The effect of Cornus mas extract on blood glucose, lipids profiles and leptin in postmenopausal women: An double blind clinical trial

Protocol summary

Summary

Objectives: The aim of this double-blind Randomized Controlled Trial study is evaluation of the effect of Cornus mas extract on lipids and blood glucose profiles and leptin in postmenopausal women. Study population and sample size: 84 menopause women (45 to 60 years old) referred to Rassol Akram hospital in Tehran. Inclusion and exclusion criteria: women with menopause who have experienced at least one year after amenorrhea history. They shouldn't: have history of malignancies, have active hepatic or renal disease, take HRT or take progesterone, intake of medicines which have effect on blood sugar or blood lipids and consumption of cornus mas. Samples will be divided into two groups to take 3 capsules containing 300mg Cornus mas extract or placebo starch powder for 8 weeks. Randomization will be done using a software through a computer. At the start of intervention, questionnaires of 24-hour Dietary Recall, physical activity (IPAQ), and general information will be filled out; height and weight will be measured, too. Afterwards 10cc venous blood sample will be taken to measure FBS, Serum Insulin, lipid profiles including Total cholesterol, HDL-cholesterol, LDL-cholesterol, TG and also ApoA1, Apob100, Leptin level, and Fibrinogen level. At the end of the intervention blood sample will be taken again and aforementioned tests will be repeated again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610259472N10**
Registration date: **2016-12-20, 1395/09/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-20, 1395/09/30

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4750

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aryaeian.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-10-29, 1395/08/08

Expected recruitment end date

2017-10-30, 1396/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cornus mas extract on blood glucose, lipids profiles and leptin in postmenopausal women: An double blind clinical trial

Public title

The effect of Cornus mas extract on Blood Glucose and lipids in postmenopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: at least 12 month of amenorrhea; No history of allergies to cornus mas fruit and products; No HRT or other menopausal treatments during last 6 months; no intake of progesterone; No intake of medicines which have effect on blood sugar, blood pressure, or blood lipids; No abnormal vaginal bleeding; No kidney or liver active illness or Inflammation (No history of Malignity); No consumption of soy or vegan diet; No history of thromboembolism; No consumption of Nutritional supplement in the past 3 months (Omega 3 and antioxidant); No drinking alcohol or smoking habit ; ability to recognize and understand the purpose of study; ability to read and write Exclusion criteria: history of allergies to cornus mas fruit and products; HRT or other menopausal treatments during last 6 months; Hysterectomy; intake of progesterone; intake of medicines which have effect on blood sugar, blood pressure, or blood lipids; abnormal vaginal bleeding; kidney or liver active illness or Inflammation (history of Malignity); consumption of soy or vegan diet; history of thromboembolism; consumption of Nutritional supplement in the past 3 months (Omega 3 and antioxidant); drinking or smoking habit

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

Randomization will be done using a software through a computer.

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 , The intersection

of Sheikh Fazlallah and Shahid Chamran, Shahid Hemman highway

City

Tehran

Postal code

Approval date

2016-09-24, 1395/07/03

Ethics committee reference number

IR.IUMS.REC 1395.9313680004

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

before intervention, after intervention

Method of measurement

biochemical tests

2

Description

Serum fasting insulin

Timepoint

Before intervention, after intervention

Method of measurement

Biochemical tests

3

Description

Serum fasting cholesterol

Timepoint

Before intervention, after intervention

Method of measurement

Biochemical tests

4

Description

Serum fasting triglycerid

Timepoint

Before intervention, after intervention

Method of measurement

Biochemical tests

5

Description

LDL cholesterol
Timepoint
Before intervention, after intervention
Method of measurement
Biochemical tests

6

Description
HDL cholesterol
Timepoint
Before intervention, after 2 month intervention
Method of measurement
Biochemical tests

7

Description
ApoA1
Timepoint
Before intervention, after intervention
Method of measurement
Biochemical tests

8

Description
ApoB100
Timepoint
Before intervention, after intervention
Method of measurement
Biochemical tests

9

Description
Leptin
Timepoint
Before intervention, after intervention
Method of measurement
Biochemical tests

Secondary outcomes

1

Description
Fibrinogen
Timepoint
Before intervention, after intervention
Method of measurement
Biochemical tests

Intervention groups

1

Description
The intervention group will receive 3 capsules containing 300 mg of powdered Cornus mas, daily, for 8 weeks. These capsules have been produced by Barij Essence Pharmaceutical Company

Category
Treatment - Drugs

2

Description
Control group will receive 3 capsules containing 300 mg starch powder as placebo, daily, for 8 weeks, produced by Barij Essence Pharmaceutical Company

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-e-akram hospital
Full name of responsible person
Dr. Naheed Aryaeian
Street address
Niayesh Av, 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 Ali Javad Moosavi
Street address
Iran University of Medical Sciences, The intersection of Sheikh Fazlallah and Shahid Chamran, Shahid 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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Naheed Aryaeian

Position

Phd in Nutrition

Other areas of specialty/work**Street address**

Nutrition Department, School of public health, Iran University of Medical Sciences, the intersection of Sheikh Fazlallah and Chamran, Shahid Hemmat highway

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Full name of responsible person

Afsane Gholamrezayi

Position

Master degree student of nutrition

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City

Tehran

Postal code**Phone**

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