Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 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-chol,LDL-chol, 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
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Iran (Islamic Republic of)
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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 cholestrol

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 cholestrol

Timepoint

Before intervention, after intervention

Method of measurement

Biochemical tests

6

Description

HDL cholestrol

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

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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

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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

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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