

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effects of *Elaeagnus angustifolia* L. on the lipid profiles in menopause women

Protocol summary

Summary

Goal key: Study of the effects of *Elaeagnus angustifolia*.L. on the lipid profile in menopausal women In Ancient Iran,*Elaeagnus angustifolia*.L is a symbol of reproduction. In addition, it is a symbol of women's fertility. this plant has glucose and fructose are the most important carbohydrates and two phytosterols have been detected in *Eangustifolia* L. phyto estrogen is similar to estrogen. phytoestrogen is an estrogenic agonist and can induce similar effects in postmenopausal women.Although the efficacy of this plant in various cases such as fever, jaundice, ulcers and lung problems such as asthma and dyspnea, nausea, vomiting, amoeba diarrhea, vomiting, rheumatoid arthritis and etc been investigated, Its effect has not yet been studied in postmenopausal women. If the *Eangustifolia* L can have an effect on the estrogen secretion effect on lipid profiles in postmenopausal women, it can be a good food option for women after menopause. method: referring to the Kamali clinic and oral invitation to collaborate, they will start randomly with the questionnaire of volunteers for their collaboration in the research. There will be 30 volunteers in each intervention and placebo group.this clinical trial is double blind and parallel, after the initial tests, 60 women will be selected to participate in the project. inclusion criteria: The menopausal women age of 40-70 with a serum lipid level of 200-300 mg / ml and a risk factor for not using the drug to reduce this lipid level are invited to this study. exclusion criteria: patient who suffer from cardiovascular, renal, and metabolic diseases such as diabetes, or psychosocial drugs or cigarettes, hookahs, alcoholics, and opiates, are excluded from the study. Interventions: Intervention group: 30 ladies receiving 15 grams per day of fine fruit powder for 10 weeks. placebo group: 30 ladies receiving 15 grams per day of isomalt and corn starch for 10 weeks. Main outcome variables: Insulin, LDL, HDL, TG, blood pressure, HbA1C

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017073132795N3**

Registration date: **2017-10-11, 1396/07/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-11, 1396/07/19

Registrant information

Name

Arezou Rezaei

Name of organization / entity

Damghan university

Country

Iran (Islamic Republic of)

Phone

+98 23 3522 0081

Email address

arezaei@du.ac.ir

Recruitment status

Recruitment complete

Funding source

Damghan UniversityAlborz University

Expected recruitment start date

2017-08-05, 1396/05/14

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of *Elaeagnus angustifolia* L. on the lipid profiles in menopause women

Public title

Effects of *Elaeagnus angustifolia* L. on lipid profile in menopause women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Postmenopausal women aged 70-40 with a serum lipid level of 200-300 mg / ml and no risk factor for using the drug to lower this lipid level are invited to this study. Major exclusion criteria: The women who suffering from cardiovascular diseases; renal and metabolic disorders such as diabetes; those using psychiatric drugs; smoking tobacco or consuming alcohol or narcotic agents are excluded from the study.

Age

From **40 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, administrative city, north Taleghani avenue, Karaj, Alborz

City

Karaj

Postal code

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

Abzums.Rec.1396.87

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.9

ICD-10 code description

Menopausal and perimenopausal disorder, unspecified

Primary outcomes

1

Description

LDL

Timepoint

Before the start of the trial and 10 weeks after taking the drug or placebo

Method of measurement

Standards of medical diagnostic laboratories

2

Description

HDL

Timepoint

Before the start of the trial and 10 weeks after taking the drug or placebo

Method of measurement

Standards of medical diagnostic laboratories

3

Description

Triglyceride

Timepoint

Before the start of the trial and 10 weeks after taking the drug or placebo

Method of measurement

Standards of medical diagnostic laboratories

4

Description

Insulin

Timepoint

Before the start of the trial and 10 weeks after taking the drug or placebo

Method of measurement

Standards of medical diagnostic laboratories

5

Description

HbA1c

Timepoint

Before the start of the trial and 10 weeks after taking the drug or placebo

Method of measurement

Standards of medical diagnostic laboratories

6

Description

Blood pressure

Timepoint

Before the start of the trial and 10 weeks after taking the drug or placebo

Method of measurement

Standards of medical diagnostic laboratories

7

Description

Total Protein

Timepoint

Before the start of the trial and 10 weeks after taking the drug or placebo

Method of measurement

Standards of medical diagnostic laboratories

Secondary outcomes

1

Description

Constipation, Abdominal Pain

Timepoint

End of the course after 10 weeks

Method of measurement

Standards of medical diagnostic laboratories

Intervention groups

1

Description

Intervention group: Elaeagnus angustifolia L powder, 15 g / day longer 10 weeks.

Category

Treatment - Drugs

2

Description

Control group(placebo):7.5 g isomalt and 7.5 g corn starch longer 10 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Clinic

Full name of responsible person

Dr. Bita Badehnoosh

Street address

Kamali clinic, after the first underpass, Shohada square toward foursquare Tleghani, Kraj

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Damghan university

Full name of responsible person

Dr Seyed Ali Pour Mousavi,Vice chancellor for research

Street address

Vice chancellor for research,Damghan university, University square, Damghan city.

City

Damghan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Damghan university

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Alborz university of medical sciences

Full name of responsible person

Dr Mohammad Noori Sepehr, Vice chancellor for research

Street address

Vice chancellor for research, Alborz university of medical sciences, administrative city, Taleghani square, Karaj

City

Karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz university of medical sciences

Proportion provided by this source

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

3

Sponsor

Name of organization / entity

Iran Zamin laboratory

Full name of responsible person

Alireza Mohammad Yari

Street address

Iran Zamin laboratory, underground of DR Asgari drugstore, side of Eram tower, Taleghani intersection, Karaj

City

Karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran Zamin laboratory

Proportion provided by this source

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

Damghan University

Full name of responsible person

Mahzad SHAabani

Position

Masters student

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work

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Web page address

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