Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 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)
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+98 23 3522 0081
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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Damghan university/Alborz University of Medical Sciences

Full name of responsible person

Dr Arezoo Rezaei/Dr BitaBadehnoosh

Position

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Other areas of specialty/work

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Position

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Other areas of specialty/work

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Email

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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