Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Effects of Elaeagnus angustifolia L. on the sex hormone profiles in menopause women

Protocol summary

Summary

In postmenopausal women, the level of sex hormones changes due to the end of ovarian function. Because of the significant and varied effects of sex hormones, especially Estrogen, on the central nervous system, bone, heart, liver and skin, the effect of these hormonal changes on the different aspects of women's health is significant and important. In postmenopausal women, phytoestrogens can act as an estrogenic agonist. Elaeagnus angustifolia L. or Russian olive, have a lot of valuable compounds. Although its efficacy has been studied in various cases, such as Rheumatoid arthritis, Gastric ulcer, etc., its effect has not yet been studied in postmenopausal women. This research is performed by simple random sampling of two intervention and control groups. In the initial assessment, blood pressure, heart rate, and lipid profiles of individuals are measured. In each group, there are 30 menopausal women aged 45-70, living in the Alborz province who will receive 15 grams of drug (full-grain Elaeagnus angustifolia L. powder) and placebo (combined with 7.5 grams of Corn Starch and 7.5 grams of Isomalt) per day for 10 weeks each day in parallel. Postmenopausal women with cardiovascular, renal and metabolic diseases, such as diabetes, as well as women who use psychosocial drugs or cigarettes, hookahs, alcoholic and narcotic drugs, or serum lipid levels of 200-300 mg/ml , will be excluded. The Estrogen, Progesterone, Testosterone, FSH and LH levels will be investigated at the beginning and at the end of this ten week period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030932795N2**
Registration date: **2017-09-11, 1396/06/20**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-09-11, 1396/06/20

Registrant information

Name
Arezou Rezaei
Name of organization / entity
Damghan university
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Research deputy of Damghan UniversityResearch deputy of Alborz 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 sex hormone profiles in menopause women

Public title

Effects of Elaeagnus angustifolia L. on the sex hormone profiles in menopause women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All women aged 40-70 with serum lipid levels of 200-300 mg/dl without any risk factor for not using medicine to decrease the lipid level are included in this trial. Exclusion criteria: The women who suffer from ccardiovascular 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

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. 1396.88

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

Estradiol

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

Progesterone

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

Testosterone

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

FSH (Follicle stimulating hormone)

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

LH (Luteinizing hormone)

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

Timepoint
After the start of the trial and up to 10 weeks after taking the drug
Method of measurement
Questionnaire and weekly phone calls

2

Description
Abdominal Pain
Timepoint
After the start of the trial and up to 10 weeks after taking the drug
Method of measurement
Questionnaire and weekly phone calls

Intervention groups

1

Description
Intervention group:Elaeagnus angustifolia L powder, 15 g / day
Category
Treatment - Drugs

2

Description
Control group (placebo): 7.5 g Isomalt and 7.5 g Corn starch / day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Clinic
Full name of responsible person
Dr. Bita Badehnoosh
Street address
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Damghan University- Alborz University
Full name of responsible person
Arezou Rezaei, Bita Badehnoosh
Street address
Damghan University, University Square, Damghan city / Alborz University of Medical Sciences, Administrative City, Taleghani square, karaj
City
Damghan, Karaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Damghan University- Alborz University
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
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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