Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Study of the effects of Elaeagnus angustifolia L. fruit on the profile of hormones and lipids and genital infectious in menopausal women refer to Kamali hospital in 1396

Protocol summary

Study aim
Determination of the effects of Elaeagnus angustifolia L. fruit on the profile of hormones and lipids and genital infectious in menopausal women.

Design
A clinical trial with a parallel control group, double blind, randomized.

Settings and conduct
Parallel, Double-blind, Kamali Clinic

Participants/Inclusion and 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

Intervention groups
Intervention group: Elaeagnus angustifolia L powder, 15 g / day longer 10 weeks. Control group(placebo):7.5 g isomalt and 7.5 g corn starch longer 10 weeks.

Main outcome variables
Estradiol, Progesterone, Testosterone, FSH and LH, TSH, Prolactin, Cortisol, DHEA-SO4, Insulin, FBS, Hemoglobin A1c, Total protein, Vitamin D, Pap smear, Urine analysis and culture, Blood pressure and Heart rate, LDL, HDL, Triglyceride, Cholesterol and Vaginal culture.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170227032795N4**
Registration date: **2018-07-26, 1397/05/04**
Registration timing: **registered_while_recruiting**
Last update: **2018-07-26, 1397/05/04**
Update count: **0**

Registration date
2018-07-26, 1397/05/04

Registrant information

Name
Arezou Rezaei

Name of organization / entity
Damghan university

Country
Iran (Islamic Republic of)

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+98 23 3522 0081

Email address
arezaei@du.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-08-05, 1396/05/14

Expected recruitment end date
2017-10-23, 1396/08/01

Actual recruitment start date
2017-08-05, 1396/05/14

Actual recruitment end date
2018-10-02, 1397/07/10

Trial completion date
empty

Scientific title
Study of the effects of Elaeagnus angustifolia L. fruit on the profile of hormones and lipids and genital infectious in menopausal women refer to Kamali hospital in 1396

Public title
Study of the effects of Elaeagnus angustifolia L. fruit on the profile of hormones and lipids and genital infectious

in menopausal women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal women aged 40-70. Serum lipid level of 200-300 mg / ml. No risk factor for using the drug to lower this lipid level.

Exclusion criteria:

Cardiovascular diseases. Renal diseases. Metabolic disorders such as diabetes. Those using psychiatric drugs. Having destructive habits like cigarettes, hookahs, consuming alcohol and drugs.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling method was used to randomize distribution of subjects in two groups of intervention and control group. The numbers 1 to 60 were written in the same color and shape paper. The paper was put in a pot after folding. Then the bowl components were stirred. By the person who did not have a role in this project, the paper was taken randomly. The first 30 numbers that came out of the bowl were intended for people who are supposed to be in the blue group.The 30 numbers remained in the bowl, the red group was considered.

Blinding (investigator's opinion)

Double blinded

Blinding description

By the person who does not play a role in this project, the coordination of drug and placebo packaging is performed in two packages with different color schemes. Supervisors and project students, as well as those involved in clinical trials, are unaware of the nature of these packages until the end of the design and receiving the latest test results and analysis of the data.

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

Alborz

Province

Alborz

Postal code

3149779453

Approval date

2018-03-10, 1396/12/19

Ethics committee reference number

Abzums.Rec.1396.162

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

8

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

9

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

10

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

11

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

12

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

13

Description

DHEA-SO4

Timepoint

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

Method of measurement

Standards of medical diagnostic laboratories

14

Description

TSH

Timepoint

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

Method of measurement

Standards of medical diagnostic laboratories

15

Description

Urinalysis and culture

Timepoint

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

Method of measurement

Standards of medical diagnostic laboratories

16

Description
heart beat
Timepoint
Before the start of the trial and 10 weeks after taking the drug or placebo
Method of measurement
Standards of medical diagnostic laboratories

17

Description
Vitamin D3
Timepoint
Before the start of the trial and 10 weeks after taking the drug or placebo
Method of measurement
Standards of medical diagnostic laboratories

18

Description
Pap smear
Timepoint
Before the start of the trial
Method of measurement
Standards of medical diagnostic laboratories

19

Description
Prolactin
Timepoint
Before the start of the trial and 10 weeks after taking the drug or placebo
Method of measurement
Standards of medical diagnostic laboratories

20

Description
Vaginal culture
Timepoint
Before the start of the trial and 10 weeks after taking the drug or placebo
Method of measurement
Standards of medical diagnostic laboratories

21

Description
Cholesterol
Timepoint
Before the start of the trial and 10 weeks after taking the drug or placebo
Method of measurement
Standards of medical diagnostic laboratories

22

Description
Cortisol
Timepoint
Before the start of the trial and 10 weeks after taking the drug or placebo
Method of measurement
Standards of medical diagnostic laboratories

23

Description
FBS(Fasting blood sugar)
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr Mohammad Noori Sepehr, Vice chancellor for research
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Vice chancellor for research, Alborz university of medical sciences, administrative city, Taleghani square, Karaj
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Email
dr.noorisepehr@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj University of Medical Sciences
Proportion provided by this source
45
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor
Name of organization / entity
Damghan university
Full name of responsible person
Dr Gholamhossein Grivani ,Vice chancellor for research
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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
55
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
University of Damghan
Full name of responsible person
Farzaneh Emami Nia
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Biochemistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
We will not disclose the private information of the participants in the project.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All information for study variables will be published (Estradiol, Progesterone, Testosterone, FSH and LH, TSH, Prolactin, Cortisol, DHEA-SO4, Insulin, FBS, Hemoglobin A1c, Total protein, Vitamin D, Pap smear, Urine analysis and culture, Blood pressure and Heart rate, LDL, HDL, Triglyceride, Cholesterol and Vaginal culture) in valid scientific papers.

When the data will become available and for how long
The start of the access period will be 6 months after the publication of the results.

To whom data/document is available
Results are unknown yet.

Under which criteria data/document could be used
After publishing the information in the articles, the data will be available to other researchers as well.

From where data/document is obtainable
Mobile phone Dr. Arezou Rezaei: +98 912 332 5792 E-mail address Dr. Arezou Rezaei: arezaei@du.ac.ir

What processes are involved for a request to access data/document
Once the research, analysis and publication period have been completed, email is available to researcher (arezaei@du.ac.ir) .

Comments