

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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)

###### Phone

+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

##### **City**

Karaj

##### **Province**

Alborz

##### **Postal code**

1941713713

**Phone**  
+98 26 3226 8914  
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b\_badehnoosh@yahoo.com

## 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  
**Street address**  
Vice chancellor for research, Alborz university of medical sciences, administrative city, Taleghani square, Karaj  
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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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grivani@du.ac.ir

**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  
**Position**  
Masters student  
**Latest degree**  
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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.Bita Badehnoosh  
**Position**

Damghan University faculty/ Alborz Medical Science faculty

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Damghan University

**Full name of responsible person**

Arezou Rezaei

**Position**

Biochemistry Phd

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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**