

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Flower Extract of *Elaeagnus Angustifolia* on Sexual Functioning in Menopausal Women

#### Protocol summary

##### Study aim

Determining the effect of elder flower extract on sexual function of postmenopausal women

##### Design

Clinical trial with control group, with parallel groups, three-blind, randomized, phase 2 on 68 patients. Sealed envelope software was used for randomization.

##### Settings and conduct

The samples taken from the health centers of Kashan city are randomly assigned to two control and test groups. The intervention group will receive the drug and the control group will receive the placebo within the specified period. The questionnaire is reviewed at the beginning, end and one month after the end of the intervention. The first researcher (the drugs will be placed in the same packages and will be marked with a code), the research samples and the statistical analyst (the names of the groups will be recorded in SPSS with abbreviations) will not have any information about the names of the groups.

##### Participants/Inclusion and exclusion criteria

Entry: married postmenopausal women aged 50 to 65 years. Getting a score less than 28 from the questionnaire of women's sexual performance. lack of medical prohibition and lack of treatment and drugs affecting sexual performance; Exit: Loss of the sample or her spouse during the study. Not taking medicine for 4 consecutive days. The individual's unwillingness to continue participating in the study.

##### Intervention groups

The intervention group received hydroalcoholic extract of elderflower and the control group received corn starch in the form of 1000 mg capsules twice a day (1 every 12 hours) for 35 days. These capsules did not differ from each other in appearance.

##### Main outcome variables

sexual function

#### General information

##### Reason for update

Reason for updating the profile and request from a foreign journal to update the exact sampling time

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100124003146N12**  
Registration date: **2023-11-13, 1402/08/22**  
Registration timing: **prospective**

Last update: **2025-07-31, 1404/05/09**

Update count: **1**

##### Registration date

2023-11-13, 1402/08/22

##### Registrant information

###### Name

Ismail Azizi-Fini

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0021

###### Email address

azizi-es@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-21, 1402/08/30

##### Expected recruitment end date

2024-01-20, 1402/10/30

##### Actual recruitment start date

2023-11-21, 1402/08/30

##### Actual recruitment end date

2024-01-20, 1402/10/30

##### Trial completion date

2024-01-20, 1402/10/30

## Scientific title

The Effect of Flower Extract of *Elaeagnus Angustifolia* on Sexual Functioning in Menopausal Women

## Public title

The Effect of Flower Extract of *Elaeagnus Angustifolia* on Sexual Functioning in Menopausal Women

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

being married Being Iranian Getting a score of less than 28 on the questionnaire on women's sexual performance index over 55 years old Having regular sex with your spouse Menopause diagnosed by a gynecologist No history of uterine or breast cancer Not being treated with chemotherapy or radiotherapy

### Exclusion criteria:

Unwillingness to participate in the study Taking antidepressants or drugs related to sexual performance having cognitive impairment based on the MMSE questionnaire (cutoff point 19) Having a medical prohibition to have sex for the spouse, such as heart attacks or heart failure A person suffering from chronic and active diseases that prevent sexual intercourse Hormone therapy (estrogen, progesterone, testosterone) in the last month

## Age

From **50 years** old to **65 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

- Participant
- Investigator
- Data analyser

## Sample size

Target sample size: **68**

Actual sample size reached: **68**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The samples will be randomly placed in two groups (test: A and control: B) based on the list prepared from the online randomization software and the address <https://www.sealedenvelope.com/simple-randomiser/v1/lists> . Random blocks of 4 will be selected.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The first researcher, the research samples and the statistical analyst will not have any information about the names of the groups.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

##### Street address

5th Kilometer Qotb Ravandi Blouvar

##### City

kashan

##### Province

Isfahan

##### Postal code

8715981151

#### Approval date

2023-08-19, 1402/05/28

#### Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1402.030

## Health conditions studied

### 1

#### Description of health condition studied

sexual function

#### ICD-10 code

E28.310

#### ICD-10 code description

Symptomatic premature menopause

## Primary outcomes

### 1

#### Description

The sexual performance score of postmenopausal women is less than 28 from the FSFI questionnaire

#### Timepoint

At the beginning of the study (before the start of the intervention), the end of the intervention (35 days), one month after the end of the intervention

#### Method of measurement

Female Sexual Function Index

## Secondary outcomes

### 1

#### Description

Anxiety

#### Timepoint

At the beginning of the study (before the start of the intervention), the end of the intervention, one month after the end of the intervention

#### Method of measurement

Beck Anxiety Inventory

## 2

### **Description**

Sleep quality

### **Timepoint**

At the beginning of the study (before the start of the intervention), the end of the intervention, one month after the end of the intervention

### **Method of measurement**

Pittsburgh Sleep Quality Index

## 3

### **Description**

Number of times of intercourse per month

### **Timepoint**

At the beginning of the study (before the start of the intervention), the end of the intervention, one month after the end of the intervention

### **Method of measurement**

Questionnaire (one question about the number of sexual intercourses per month)

## **Intervention groups**

### 1

#### **Description**

Intervention group: In this study, the hydroalcoholic extract of elderflower will be prepared in Asha Medicinal Herbs Trading Company, which will be purchased after the approval of the plan by the ethics committee and will be prepared in 1000 mg capsules and will be provided to the research units by a gynecologist.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Postmenopausal women who are randomly assigned to the control group will receive 1000 mg capsules containing corn starch (manufactured by Tardak Company (1 piece every 12 hours) for 35 days, which has no difference in appearance with elderflower extract.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Beheshti Hospital

##### **Full name of responsible person**

Faeze Lotfi Jalalabadi

##### **Street address**

Kashan Qutb Ravandi Blvd

##### **City**

Kashan

##### **Province**

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##### **Postal code**

8715981151

##### **Phone**

+98 31 5554 0026

##### **Email**

f.l.heaven.s@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kashan University of Medical Sciences

##### **Full name of responsible person**

Gholam Ali Hamidi

##### **Street address**

Kashan Qutb Ravandi Blvd. University of Medical Sciences

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##### **Phone**

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##### **Email**

f.l.heaven.s@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Kashan University of Medical Sciences

#### **Proportion provided by this source**

100

#### **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**

Kashan University of Medical Sciences

##### **Full name of responsible person**

Ismail Azizi Fini

##### **Position**

Associate Professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Nursery

**Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Ismail Azizi-Fini

**Position**

Associated professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Ismail Azizi-Fini

**Position**

Associated professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Undecided - It is not yet known if there will be 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**

The results of the main outcome will be published.

**When the data will become available and for how long**

Access will start from the time the results are printed to forever.

**To whom data/document is available**

Academic and industrial researchers are allowed to submit data requests.

**Under which criteria data/document could be used**

The applicant must first clearly state the purpose of the data request to the person in charge, and if approved by the university's research council, non-identifiable data will be provided to him.

**From where data/document is obtainable**

Dr. Ismail Azizi Fini, email: azizifinies@yahoo.com

**What processes are involved for a request to access data/document**

After sending the request via email, it will be in the shortest time.

**Comments**