

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of the hydro alcoholic extract of the flower of *Elaeagnus angustifolia* L on the sexual performance of women, a randomized clinical trial with a double-blind control

#### Protocol summary

##### Study aim

Determining the effect of hydro alcoholic extract of *Elaeagnus angustifolia* L. on women's sexual performance

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 58 patients, a computer site is used for randomization

##### Settings and conduct

The location is Masoumeh Hospital, Kermanshah. After the patients are allowed to participate in the study, the subjects are randomly assigned to the intervention and treatment group, and the intervention subjects take one cc of medicine and the placebo subjects take 1 cc of placebo daily. drugs will be placed in sealed envelopes with predetermined codes by a person who is not involved in providing the treatment.

##### Participants/Inclusion and exclusion criteria

Married women aged 18 to 54 with a complaint of decreased sexual performance and a score of less than 28 from the sexual performance questionnaire conditions of non-entry include pregnancy and breastfeeding, oophorectomy, menopause, the use of some hormone-based drugs, or the individual's unwillingness to continue participating in the study

##### Intervention groups

The intervention is the hydro alcoholic extract of *Elaeagnus angustifolia* L. and the intervention group will consume one cc equivalent to 20 drops of the medicine daily for 30 days, and the people in the control group will also consume one cc of the placebo daily for 30 days.

##### Main outcome variables

The main variable of the questionnaire is the sexual function, which has 6 fields, including the fields of desire, slippery, arousal, satisfaction, orgasm, and pain. The changes in scores will be checked once overall and once in the desired areas before the intervention and once

after taking the drug at the end of the study.

Progesterone and estrogen hormone changes will be checked once before taking the drug and once after taking the drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230501058039N1**

Registration date: **2023-05-06, 1402/02/16**

Registration timing: **prospective**

Last update: **2023-05-06, 1402/02/16**

Update count: **0**

##### Registration date

2023-05-06, 1402/02/16

##### Registrant information

##### Name

Maryam Dezhkameh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3827 0568

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-31, 1402/03/10

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of the hydro alcoholic extract of the flower of *Elaeagnus angustifolia* L on the sexual performance of women, a randomized clinical trial with a double-blind control

**Public title**  
Investigating the effect of the hydro alcoholic extract of the flower of *Elaeagnus angustifolia* L on the sexual performance of women

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Married Having a constant sexual partner Healthy pelvic examination Age 18 to 54 Deficiency or loss of sexual desire caused by stress Normal and regular menstrual cycle Obtaining a score less than 28 from the sexual dysfunction questionnaire.

**Exclusion criteria:**

Pregnancy and breastfeeding Menopause Oophorectomy Consumption of alcohol and tobacco Wife's sexual problem Getting any disease during the study The patient's unwillingness to continue Diabetes, kidney and liver diseases, hypothyroidism, cardiovascular-cerebrovascular disease, cancer, mental disorder with drug use, use of any contraceptive and hormone-based drugs that affect libido, such as androgens, anti-androgens, SSRI, tricyclic antidepressants, progestin's and  $\alpha$ -blockers  $\alpha$

**Age**  
From **18 years** old to **54 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **58**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization method is block. The randomization unit is individual. The randomization tool is a statistical software, and for concealment, block randomization with 4 or 6 blocks and one-to-one allocation ratio will be used.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The clinician and the patient are blinded to the treatment received. Medications will be placed in sealed envelopes with predetermined codes by a person who is not involved in providing the treatment

**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Kermanshah University of Medical Sciences

**Street address**

Building No, 2Shahid Beheshti Boulevard,Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2023-04-11, 1402/01/22

**Ethics committee reference number**

IR.KUMS.REC.1402.030

**Health conditions studied**

1

**Description of health condition studied**

Decreased sexual performance in women

**ICD-10 code**

F52.0

**ICD-10 code description**

Hypoactive sexual desire disorder

**Primary outcomes**

1

**Description**

Comparison of changes in the total score and domains of the sexual function questionnaire (FSFI) after consuming the hydro alcoholic extract of *Elaeagnus angustifolia* L

**Timepoint**

The total score of the questionnaire will be checked before taking the medicine and 30 days after taking the medicine

**Method of measurement**

Rosen sexual function questionnaire

**Secondary outcomes**

**1**

**Description**

Comparison of progesterone and estrogen hormone changes

**Timepoint**

The amount of hormones will be measured once at the beginning of the study and once after 30 days at the end of the study

**Method of measurement**

Monobind kit

**Intervention groups**

**1**

**Description**

Intervention group: Intervention group: The drug used is the hydro alcoholic extract of *Elaeagnus angustifolia* L flower, which was prepared by the Soxhlet method by Eugene Sinapjoh Pharmaceutical Company. The patients will take 1 cc daily for 30 days

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Hazrat Masoume Hospital, Kermanshah

**Full name of responsible person**

Gholamreza Abdoli

**Street address**

Taghbestan Blvd, Kermanshah

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Cyrus Galilee

**Street address**

Research and Technology Vice-Chancellor Building  
No, Shahid Beheshti Blvd

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research\_it@kums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Gholamreza Abdoli

**Position**

assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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Isar Square, Kermanshah

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**Person responsible for updating data****Contact****Name of organization / entity**

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Gholamreza Abdoli

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

Isar Square, Kermanshah

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

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

No - There is not 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