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)

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+98 83 3827 0568

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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 α-blockers α

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
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Cyrus Galilee
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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
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assistant professor
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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