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. Sealedenvelope 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
Isfehan

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
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Phone
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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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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

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Person responsible for updating data

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azizi-es@kaums.ac.ir

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