Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

The effect of powder of Elaeagnus angustifolia flower on sexual dysfunction in women with multiple sclerosis (MS): A double-blind randomized clinical trial

Protocol summary

Study aim
Determining the effect of powder of Elaeagnus angustifolia flower on sexual dysfunction in women with MS referring to the MS clinic of Shefa Hospital - Kerman

Design
This research, in the form of a double-blind randomized clinical trial, will investigate the effectiveness of Elaeagnus angustifolia flower powder on sexual dysfunction in women with MS.

Settings and conduct
This research will be conducted in the MS clinic of Shefa-Kerman Hospital on at least 92 MS patients with sexual dysfunction. After packaging, the drug and placebo will be coded as A and B by the pharmacist. These codes will be attached with a label on the drug and placebo package. Only pharmacists and biostatisticians will know how to assign these codes to drugs and placebos. Then they will be provided to the researcher. Neither the researcher nor the patient will know how to assign the codes to the drug or placebo. Finally, the codes and data will be provided to a statistician and analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women with MS of reproductive age and married with a constant sexual partner Sexual dysfunction confirmed by the test (Female Sexual Function Index (FSFI). Normal pelvic examination Pap smear negative in the last six months Natural examination of the breasts Exclusion criteria: suffering from a serious disease other than MS, Any history of genital or gastrointestinal or breast cancer, Suffering from depression or other mental disorders and taking antidepressants Pregnancy and breastfeeding

Intervention groups
The drug group will receive 5 grams of encapsulated Elaeagnus angustifolia flower powder and the placebo group will receive 5 grams of encapsulated starch powder for one month.

Main outcome variables
Severity of sexual dysfunction

General information

Reason for update
After further investigation, we found studies that used flower powder of Elaeagnus angustifolia to improve sexual dysfunction in women. Accordingly, after consulting with a traditional pharmacy specialist who is collaborating with us in this project, we concluded to use flower powder directly . In this regard, the items related to the title, implementation method, and type of intervention were updated.

Acronym
MS

IRCT registration information
IRCT registration number: **IRCT20161108030776N4**
Registration date: **2024-06-08, 1403/03/19**
Registration timing: **prospective**

Last update: **2025-06-01, 1404/03/11**
Update count: **1**

Registration date
2024-06-08, 1403/03/19

Registrant information

Name
Mohadese Kamali
Name of organization / entity
Kerman University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01

Expected recruitment end date
2025-08-22, 1404/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of powder of Elaeagnus angustifolia flower on sexual dysfunction in women with multiple sclerosis (MS): A double-blind randomized clinical trial

Public title
The effect of Elaeagnus angustifolia flower on female sexual dysfunction in MS

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with MS in reproductive age and meta-males who have a constant sexual partner Sexual dysfunction confirmed by the test (Female Sexual Function Index (FSFI) Normal pelvic examination Pap smear negative in the last six months Normal breast examination

Exclusion criteria:
Suffering from a serious disease other than MS (any disease other than MS that requires the participant to use non-MS medications during the study) Any history of genital or gastrointestinal or breast cancer pregnancy and breastfeeding Suffering from depression or other mental disordersand taking antidepressants

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two equal intervention and control groups using the random block method of four, and the codes of the patients will be provided to the biostatistics specialist and will not be opened until the end of the intervention period of the last patient and analysis.

Blinding (investigator's opinion)
Double blinded

Blinding description
After packaging, the drug and placebo are coded as A and B by the pharmacist, and these codes will be attached with a label on the drug and placebo package. Only pharmacists and biostatisticians will know how to assign these codes to drugs and placebos. Then they will be provided to the researcher. Neither the researcher nor the patient knows how to assign codes to drugs or placebos. Finally, the codes and data will be provided to the statistician and the analysis will be done.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2022-04-16, 1401/01/27

Ethics committee reference number
IR.KMU.REC.1401.020

Health conditions studied

1

Description of health condition studied
Sexual dysfunction in multiple sclerosis

ICD-10 code
F54

ICD-10 code description
Psychological and behavioral factors associated with disorders or diseases classified elsewhere

Primary outcomes

1

Description
Severity of sexual dysfunction

Timepoint

The beginning of the study, one month after the start of the study

Method of measurement

Female Sexual Function Index (FSFI) questionnaire

2

Description

quality of life

Timepoint

The beginning of the study, one month after the start of the study

Method of measurement

Questionnaire of the quality of life of MS patients named MSQOL54

3

Description

Temperament type

Timepoint

The beginning of the study

Method of measurement

Salmannejad temperament standard questionnaire

Secondary outcomes

1

Description

Any possible side effects

Timepoint

End of study

Method of measurement

Registration by the patient and questions from the patient

Intervention groups

1

Description

Intervention group: Drug group: 5 grams of elderflower powder in the form of oral capsules in two divided doses 12 hours apart for one month

Category

Treatment - Drugs

2

Description

Control group: The placebo group will receive 5 grams of starch powder in capsule form in two divided doses for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Hoda Kamali

Street address

Shafa Medical Education Research Center, Kausar Blvd.

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Kerman

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7618751151

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+98 34 3211 5780

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Hamid Sharifi

Street address

Research and Technology Office, at the beginning of Ibn Sina Street, Samiya Crossroads (Tahmasababad)

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Phone

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice President of Research and Technology of Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Mohadese Kamali

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Persian medicine, University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mohadese Kamali

Position
Assistant professorاستادیار

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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
There is no further information.

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
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available