Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of total nettle capsules on sexual desire and satisfaction of postmenopausal women aged 45-65 years

Protocol summary

Study aim
Determining the effect of nettle capsules on sexual desire and satisfaction in postmenopausal women
Design
Clinical trial with control and intervention group, with parallel groups, three-way blind, randomized with Random allocation software
Settings and conduct
Gynecological clinics of Imam Reza and Ghaem and Umm Al-Banin government hospitals and health centers under the auspices of Mashhad University of Medical Sciences
Participants/Inclusion and exclusion criteria
Menopausal women 65-45 years old Single wife Regular vaginal intercourse at least once or twice a week At least 12 months after the last menstrual period or follicle-stimulating hormone greater than 40IU No hormone therapy or sex hormone use during the 8 weeks before the study No abnormal uterine bleeding or spotting Sexual satisfaction score less than 75 and depression score less than 21, anxiety score less than 20, stress score less than 26 of DASS-21 questionnaire
Intervention groups
In the intervention group, they are asked to do it once for 4 weeks. Use nettle capsules containing 500 mg of active ingredient per day. At the end of week 4, women fill out the Halbert and Larson questionnaires again, and four weeks after treatment (end of week 8), the Halbert and Larson questionnaire will be completed again. In the placebo group, they are asked to do it once for 4 weeks. Use nettle extract capsule daily. The placebo capsule contains Oisel, which is an inert substance and has no systemic absorption. This capsule is exactly the same in appearance as the intervention.
Main outcome variables
In this study, sexual desire and satisfaction are the main variables studied. Sexual desire is examined by the Halbert Questionnaire and sexual satisfaction by the Larson Questionnaire to finally evaluate the effects of nettle pixel consumption on these two items.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210929052627N1**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **prospective**

Last update: **2022-01-10, 1400/10/20**
Update count: **0**
Registration date
2022-01-10, 1400/10/20

Registrant information
Name
Azam Azarboun
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-21, 1400/11/01
Expected recruitment end date
2022-06-22, 1401/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title

The effect of total nettle capsules on sexual desire and satisfaction of postmenopausal women aged 45-65 years

Public title

The effect of nettle capsules on sexual desire and satisfaction of postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 12 months after the last menstrual period or follicle-stimulating hormone greater than 40IU Sexual satisfaction score less than 75 and depression score less than 21, anxiety score less than 20, stress score less than 26 of DASS-21 questionnaire Menopausal women 65-45 years old Single spouse Have at least once or twice a week of normal vaginal intercourse No chronic diseases (diabetes, hypertension, fat, etc.) Lack of hormone therapy or consumption of sex hormones during the 8 weeks before the study No smoking and alcohol No abnormal uterine bleeding or spotting Lack of frequent use of other phytoestrogen drugs (soy, red clover, fenugreek, five fingers, fennel) in the past month Do not take drugs that affect sexual function by the wife or spouse Absence of known medical and psychological illnesses affecting the sexual function of oneself or one's spouse Having conscious satisfaction Iranian nationality Resident of Mashhad No history of chemotherapy and pelvic or whole body radiotherapy No history of sexually transmitted diseases, mastectomy, chlorpuraphy

Exclusion criteria:

Symptoms of drug allergy Taking any medication that affects sexual function during the study Not having sex once a week during the study Taking hormonal drugs or containing phytoestrogens during research Experience unfortunate or stressful events in the wife or her husband while studying Dissatisfaction with continued cooperation Do not take the drug for 3 consecutive times or 4 non-consecutive times

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

1

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

simple Based on sealed envelopes The random sequence of the sample is done using random allocation software in two groups A and B. Allocation concealment will be using sealed envelopes. At the beginning of the registration, the entry of the eligible participants will be opened in one of the envelopes and the assigned group will be determined and they will be given capsule A or B based on the assigned group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The subjects, analysts, evaluators, and samplers will be unaware of the intervention and control groups. The capsules of the intervention group and the placebo group are named groups A and B by the pharmacist consultant, and until the end of the study and analysis, the subjects, researchers and analysts will be unaware of the type of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of Medical Sciences

Street address

School of Nursing and Midwifery,Ibn Sina St., Ph.D. Intersection,University St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-11-07, 1400/08/16

Ethics committee reference number

IR.MUMS.REC.1400.228

Health conditions studied

1

Description of health condition studied

The effect of nettle capsule on sexual desire and satisfaction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease Sexual dysfunction covers the various ways in which an individual is unable to participate in a sexual relationship as he or she would wish. Sexual response is a psychosomatic process and both

Primary outcomes

1

Description
Sexual desire
Timepoint
Before the study, after the intervention, four weeks after the intervention
Method of measurement
Halbert Questionnaire (HISA):This questionnaire consists of 25 questions, which assess the level of sexual desire of the subject. Each item is scored on a Likert scale with 5 degrees. The score range is between 0-100. Higher scores indicate more sexual desire.

2

Description
Sexual satisfaction
Timepoint
Before the study, after the intervention, four weeks after the intervention
Method of measurement
Larson Questionnaire; The scale considered for the analysis according to the score obtained is between 125-25, so that a score less than 50 means sexual dissatisfaction, 75-51 low satisfaction, 76-100 average satisfaction and more Out of 100, it indicates high sexual satisfaction. In this study, people with a sexual satisfaction score of less than 75 are included in the study.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, after obtaining the inclusion criteria and before starting the intervention, first the Halbert sexual orientation and Larson sexual satisfaction questionnaires are filled out and after explaining the study objectives and how to use oral capsules, they are asked to Use nettle capsules containing 500 mg of active ingredient once a week. At the end of week 4, the women fill out the Halbert and Larson questionnaires again, and four weeks after treatment (end of week 8), the Halbert and Larson questionnaire will be completed again.
Category
Treatment - Drugs

2

Description
Control group: They are asked to use nettle extract capsules once a day for 4 weeks. The placebo capsule contains Oisel, which is an inert substance and has no systemic absorption. This capsule is exactly the same in appearance as the intervention. At the end of week 4, women will fill out the Halbert and Larson questionnaires again, and four weeks after treatment (at the end of the eighth week), the Halbert and Larson questionnaires will be filled out again.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza (AS) Hospital, Mashhad
Full name of responsible person
Azam Azarboun
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Imam Reza Hospital, Imam Reza Square, Ibn Sina St.,Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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School of Nursing and Midwifery, Ibn Sina St., Doctora Crossroads, Mashhad
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Azam Azarboun

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, after blinding patients' private information, all data files will be provided to researchers.

When the data will become available and for how long

6Months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions, people working in industry

Under which criteria data/document could be used

The use of information by individuals will be fully permitted subject to the names of the researchers. We are also excused from publishing patients' private information.

From where data/document is obtainable

Azam Azarboun azarbouna982@mums.ac.ir ID Tele: a.azarboon

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

My email will be texted and will be answered within one to two weeks. AzarbounA982@mums.ac.ir

Comments