Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of Vaginal cream Artemisia absinthium on Sexual function and sexual satisfaction and quality of sexual life of postmenopausal women.

Protocol summary

Study aim
Determining the effect of wormwood vaginal cream on sexual performance and satisfaction and quality of sexual life of postmenopausal women

Design
This study is a randomized clinical trial two groups (drug and placebo), three-blinds, phase 3, which will be performed on 112 women with inclusion criteria. Random allocation sequences are performed using random allocation software and block size two.

Settings and conduct
The study site is the gynecology clinic of Imam Reza (AS), Ghaem (AS) hospitals and health centers of Mashhad.At the beginning and end of the intervention, the female sexual function index, Larson sexual satisfaction and quality of sexual life and depression are completed by two groups. The researcher, participants, and data analyzer are blinded so that the creams are given to participants in the same packaging as the pharmacist consultant.

Participants/Inclusion and exclusion criteria
Inclusion criteria included age range 45-65 years, married women, having a hormonal test with FSH above 40, one year or more after the last menstrual period, having sexual activity at least twice during the month of intervention and sexual function score below 28 of the Female Sexual Function Index questionnaire and sexual satisfaction score below 75 of the Larson sexual satisfaction questionnaire. Exclusion criteria include the use of phytoestrogens such as soy, flaxseed, clover sprouts and alfalfa in the diet, infection or vaginal bleeding of unknown cause.

Intervention groups
The intervention group will use one application of wormwood cream vaginally for 4 weeks and 3 times a week. The placebo group will use the same foundation cream without wormwood extract according to the mentioned instructions.

Main outcome variables
Performance and satisfaction and quality of sexual life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210223050471N2**
Registration date: **2022-01-13, 1400/10/23**
Registration timing: **prospective**

Last update: **2022-01-13, 1400/10/23**
Update count: **0**

Registration date
2022-01-13, 1400/10/23

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-02-20, 1400/12/01
Expected recruitment end date
2022-05-22, 1401/03/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of Vaginal cream Artemisia absinthium on Sexual function and sexual satisfaction and quality of sexual life of postmenopausal women.

Public title
The effectiveness of cream Artemisia absinthium on Sexual function and sexual satisfaction and quality of sexual life .
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age ranges 45-65 years Married women Having a hormonal test with an FSH level above 40 One year or more after the last menstrual period Having sexual activity at least twice during a month of intervention time No liver, kidney, heart, thromboembolic and psychological problems No history of chemotherapy or radiation therapy to the pelvis or the whole body Lack of consumption psychiatric drugs, fluoxetine, vitamin E, propranolol and other chemical or herbal medicines that affect the symptoms of menopause Lack of consumption hormone replacement therapy Lack of consumption tobacco, alcohol or drugs Lack of depression (depression score 21 and above), no anxiety (anxiety score 15 and above), no stress (stress score 26 and above) of DASS-21 questionnaire Sexual performance score below 28 of the Female Sexual Function Index questionnaire and sexual satisfaction score below 75 of the Larson Sexual Satisfaction Questionnaire
Exclusion criteria:
Use phytoestrogens in the diet such as soy, flaxseed, clover germ and alfalfa Infection or vaginal bleeding of unknown cause
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the permutation block method is used to generate a sequence of random allocation of individuals to the study groups. Random allocation sequences are performed using random allocation software and block size two. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this research, the researcher, participants and statistical analyst are blinded. In this way, the drugs that are placed in the same boxes and named by the pharmacist consultant (no one in the study except the pharmacist consultant knows the contents of the boxes) the boxes are given to the group of participants.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the School of Nursing and Midwifery - Mashhad University of Medical Sciences
Street address
University St., Qureshi Building, Mashhad University of Medical Sciences, Vice Chancellor for Research
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Province
Razavi Khorasan
Postal code
13944-91388
Approval date
2021-11-30, 1400/09/09
Ethics committee reference number
IR.MUMS.NURSE.REC.1400.077

Health conditions studied

1

Description of health condition studied
Sexual function, sexual satisfaction, quality of sexual life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual Performance Score
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Female Sexual Function Index (FSFI)

2

Description
Sexual satisfaction score
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Larson Sexual Satisfaction Questionnaire(LSSQ)

3

Description
Sexual quality of life score
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Female Sexual Quality of Life Questionnaire(SQOL-F)

Secondary outcomes

empty

Intervention groups

1

Description
For 4 weeks and 3 times a week (before going to bed) and if you are intercourse during these 3 times 30 minutes before sexual intercourse, an applicator of 5% wormwood herbal cream will be used vaginally. In 4 weeks, 12 applicators of the cream should be used. Each applicator is equivalent to 250 mg of wormwood extract.
Category
Treatment - Drugs

2

Description
Control group: The same cream without wormwood extract for 4 weeks and 3 times a week (before bedtime) and if you have intercourse in these three times, 30 minutes before, an applicator of the cream will be used vaginally. In 4 weeks, 12 applicators of the cream should be used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Fatemeh Tara
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2

Recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
70
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
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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
The data will be shared after it becomes unrecognizable
When the data will become available and for how long
6 months after recording the results
To whom data/document is available
All researchers
Under which criteria data/document could be used
All postmenopausal women have dysfunction and sexual satisfaction and low quality of sex life
From where data/document is obtainable
Email niloofarhajatpoor@gmail.com Library of Mashhad School of Nursing to Mashhad, Daneshgah St.
What processes are involved for a request to access data/document
First, send a requested email and if you do not respond within a week, you can refer to the library of Mashhad School of Nursing.
Comments