Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of Artemisia absinthium on sexual performance and satisfaction of women of reproductive age.

Protocol summary

Study aim
Determining the effect of Artemisia absinthium vaginal gel on performance and sexual satisfaction of women of reproductive age

Design
This study is a clinical trial with a control group, with parallel groups, triple blind, randomized on 76 participants. Random allocation software will be used for randomization.

Settings and conduct
This study will be performed on 76 women referred to the gynecology clinic of Imam Reza and Ghaem hospitals of Mashhad University of Medical Sciences. After selecting the participants, the demographic information questionnaire, female sexual function index, Larson sexual satisfaction and Dass-21 are completed by two groups. 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 (none of the study people except the pharmacist consultant knows the contents of the boxes) are given to them depending on the group of participants. At the end of the research, are completed the female sexual function index and Larson sexual satisfaction .

Participants/Inclusion and exclusion criteria
Married women 18-45 years old Having vaginal sex at least once a week Sexual function score less than 28 and sexual satisfaction less than 50

Intervention groups
In the intervention group, an applicator of 5% Artemisia absinthium vaginal gel will be used for 4 weeks and 3 times a week (before going to bed). For the placebo group, the same base gel without Artemisia absinthium will be used.

Main outcome variables
Sexual function score Sexual satisfaction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210223050471N1**
Registration date: **2021-02-28, 1399/12/10**
Registration timing: **prospective**

Last update: **2021-02-28, 1399/12/10**
Update count: **0**

Registration date
2021-02-28, 1399/12/10

Registrant information

Name
niloofar Hajatpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effectiveness of Artemisia absinthium on sexual performance and satisfaction of women of reproductive age.

Public title
The effectiveness of Artemisia absinthium on sexual performance and satisfaction of women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Married women 18-45 years old Minimum literacy Having conscious satisfaction Iranian nationality Resident of Mashhad Married and only husband's wife No history of pelvic surgery Absence of infertility Do not use drugs and alcohol in a wife or spouse Absence of any sexual dysfunction in the spouse Absence of pregnancy and lactation Do not take drugs that affect sexual function by the wife or spouse No recent use of hormonal drugs Having at least once a week of normal vaginal sex Absence of abnormal vaginal bleeding Having a regular menstrual cycle with normal bleeding No history of chemotherapy and radiotherapy to the pelvis or the whole body Lack of known medical and psychological illnesses affecting the sexual function of oneself or one's spouse No depression, anxiety, severe stress Sexual function score less than 28 and sexual satisfaction score less than 50

Exclusion criteria:
Drug allergy

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
The random sequence of samples is done using random allocation software in two groups A and B Which are intervention and control groups. For Allocation concealment will be using sealed envelopes. A number of envelopes are prepared and each of the random sequences is written on a card and the cards inside the envelope are placed in order and the outer surface of the envelopes is numbered in the same order. Then envelope lids are then glued and placed in the box, respectively. At the beginning of the registration of participants, After giving the necessary explanations to each of the participants and obtaining informed consent, one of the envelopes will be opened in order for the eligible participants to arrive, and the assigned group of the participant will be determined.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug is placed in two identical boxes and none of the study subjects will be aware of the contents of the boxes except the pharmacist consultant. Depending on the group of participants, gel A or B, previously named by the pharmacist consultant, is given to participants.

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
Mashhad University of Medical Sciences, Vice Chancellor for Research, Qureshi building, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2021-01-26, 1399/11/07

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.094

Health conditions studied

1

Description of health condition studied
Sexual function

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Sexual satisfaction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function score

Timepoint

At the beginning of the study and 4 weeks after using the gel

Method of measurement

The Female Sexual Function Index Questionnaire

2

Description

Sexual satisfaction score

Timepoint

At the beginning of the study and 4 weeks after using the gel

Method of measurement

Larson Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Wormwood with the scientific name (Artemisia absinthium) belongs to the Asteraceae family and is one of the warm native plants, especially in the eastern and northern regions of Iran, and is known as Kharagoush, Gondvash, Marwa and Wormwood. Phytochemical studies of wormwood include a variety of chemical compounds including carbohydrates, alkaloids, saponins, phytosterols, proteins, amino acids, tannins, phenolic compounds, flavonoids. In this study, a vaginal gel tube of 100 g of 5% wormwood (equivalent to 250 mg of available extract) is used. Wormwood is purchased from the approved centers of the university and under the supervision of the esteemed pharmacist of the project, after grinding it, it is soaked in 70% hydroalcoholic solution for 3 days. After this, the desired hydroalcoholic extract is filtered and after removing the solvent, the final extract is obtained. Then the vaginal gel of this extract is prepared based on carbapol with a concentration of 5%. For standardization, the product in terms of total phenol will be standardized by spectrophotometric method. Then it is coded and given to women blindly and they are asked to use this gel vaginally for 4 weeks and 3 times a week (before going to bed) and in case of intercourse, 30 minutes before intercourse.

Category

Treatment - Drugs

2

Description

Control group: In the present study, placebo means a base gel (carbapol) without wormwood extract, which is prepared under the supervision of a pharmacist. The appearance of this gel is similar to the worm wood gel. The method of using this gel is similar to the main drug (wormwood gel), 4 weeks and 3 times a week (before going to bed) and in case of intercourse, 30 minutes before sexual intercourse vaginally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Mashhad

Full name of responsible person

Dr. Ali Khorsand Vakilzadeh

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2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

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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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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
Dr. Raheleh Babazadeh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
pregnancy health

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School of Nursing and Midwifery, Daneshgah Street

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Person responsible for scientific inquiries

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Position
Associate professor

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Niloofar Hajatpour

Position
Student

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Other areas of specialty/work
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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 women with dysfunction and sexual satisfaction

From where data/document is obtainable

Email niloofarhajatpoor@gmail.com Library of Mashhad School of Nursing to Mashhad, Daneshgah Street.

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