Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effects of vaginal gel of myrtus communis on Sexual Function of married women during Reproductive Ages

Protocol summary

Study aim
Determining the effect of vaginal gel on the sexual function of women of reproductive age

Design
Randomized, superiority, parallel group trial with blinded outcome assessment. Randomization was done using Random Allocation Software.

Settings and conduct
The place of study is women's clinics covered by Mashhad University of Medical Sciences and midwifery consultation clinics. The study population is women of reproductive age. The research is triple blind. For blinding, two groups were used, including the intervention group that receives the vaginal gel and the control group that receives the placebo, the vaginal gel and placebo have the same appearance. Each research unit is randomly assigned to group A or B (blinding of the research unit and the researcher), and completes the FSFI and DASS-21 form. Then they are asked to use an applicator of 5% vaginal gel or placebo 15 minutes before sexual intercourse, for 4 weeks. At the end of the 4th week, the FSFI questionnaire is filled again. The analysis is done without the knowledge of the statistical consultant of the people in the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: A married woman of reproductive age (18-40) years old; Having a sexual function score based on the FSFI questionnaire is less than 28 Having sex at least once a week; Exclusion criteria: pregnancy and breastfeeding; vaginal atrophy; Allergy to herbal substances

Intervention groups
The intervention group includes 38 people who use an applicator of 5% vaginal gel 15 minutes before sexual intercourse for 4 weeks. The control group includes 38 people who use placebo in the same way.

Main outcome variables
Sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230723058892N1**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date
2023-08-30, 1402/06/08

Registrant information

Name
bahareh khajehpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3328 8387

Email address
khajehpourbahareh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effects of vaginal gel of myrtus communis on Sexual Function of married women during Reproductive Ages

Public title

The effects of myrtus communis on Sexual Function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A married woman of reproductive age (18-40) years old Having informed consent to participate in the research Having a sexual function score based on the FSFI questionnaire is less than 28 Has a history of NVD Having sex at least once a week A resident of Mashhad or the suburbs Having at least reading and writing literacy Having a regular period cycle (26-32 days) and not having AUB Having a depression score of less than 21, anxiety less than 15, and stress less than 26 in the DASS questionnaire

Exclusion criteria:

Allergy to herbal substances or herbs pregnancy and breastfeeding infertility hormone therapy or use of sex hormones 2 months before the study Specific mental illness in couples and specific medical illness affecting sexual function in women and husbands vaginal atrophy Pelvic radiation therapy or chemotherapy to treat cancer oophorectomy early menopause uncontrolled diabetes Treatment with drugs used to reduce estrogen levels in women with endometriosis

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

The necessary sample is selected in an easy and accessible way, and then the permutation block method is used to generate the sequence of random allocation of people to the studied groups. Random allocation sequence of people will be done using Random Allocation Software and block size of four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of studied groups. There are six blocks in this study. One of the blocks is randomly selected. If the first block is AABB, the first and second people will be assigned to group A, and the third and fourth people will be assigned to group B, and this process continues until all the samples will be assigned. The characteristic of this method is that the two study groups will have equal numbers

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is a triple-blind randomized clinical trial. That is, the researcher, the research unit and the statistical consultant do not know the type of drug given (vaginal gel or placebo).The gel is made with a completely identical appearance to the placebo.

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

Baharestan dormitory 2; Medical Sciences Campus; Bahonar Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2023-07-22, 1402/04/31

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.057

Health conditions studied

1

Description of health condition studied

Sexual function and sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Sexual function score in the FSFI questionnaire

Timepoint

Measurement of sexual function at the beginning of the study (before the start of the intervention) and 4 weeks after using the vaginal gel

Method of measurement

Female Sexual Function Index Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group includes 38 people who will use an applicator of 5% case leaf vaginal gel, 15 minutes before sexual intercourse for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group:This group included 38 people who used a placebo applicator 15 minutes before sexual intercourse for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Women's Clinic of Ghaem Hospital
Full name of responsible person
Mohammad Moeini Nodeh
Street address
Qaem educational research and treatment center; Central Clinic; The beginning of Ahmedabad street; Dr. Shariati square
City
Mashhad
Province
Razavi Khorasan
Postal code
91766_99199
Phone
+98 51 3840 0001
Fax
Email
MoeiniNM@mums.ac.ir

2

Recruitment center
Name of recruitment center
Emam Reza Educational, Research and Treatment Center
Full name of responsible person
Mahmoud Mohammadzadeh Shabestari
Street address
Imam Reza hospital; Imam Reza Square; Ibn-e Sina Avenue; Mashhad; Iran
City
Mashhad
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9137913316
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shabestarim@mums.ac.ir

3

Recruitment center
Name of recruitment center
Ommol Banin hospital
Full name of responsible person
Nahid Sahebdelfar
Street address
Ommol Banin Hospital; Azadi 16th; Azadi Avenue; Mashhad; Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9144734767
Phone
+98 51 3223 1061
Email
OAH.IT@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan
Street address
Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email
presidentoffice@mums.ac.ir
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

raheleh babazadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Mashhad Faculty of Nursing and Midwifery, Ibn-e Sina St.,Doktora Crossing, Mashhad, Iran

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Raheleh Babazadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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City

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babazadehr@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Bahareh Khajehpour

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Fax

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khajehpourbahareh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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