Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The Effect of Cumin Vaginal Cream on Vaginal Atrophy, Sexual Function Index and Sexual Distress in Postmenopausal Women, Gonanbad –2022

Protocol summary

Study aim
Determining the effect of cumin vaginal cream on vaginal atrophy, sexual function and sexual distress of postmenopausal women

Design
A three-blind clinical trial

Settings and conduct
This study will be conducted in Gonabad city in health centers. The study will be triple-blind, and the researcher, the analyst, and the participant will be unaware of the content of the worms

Participants/Inclusion and exclusion criteria
Entry criteria: age between 45 and 65 years, passing 1 to 2 years since menopause, having a minimum education degree with literacy, having informed consent to participate in the research, married and monogamous, no history of pelvic surgery, no Drug and alcohol use by the woman and her husband, no use of estrogenic drugs, no vaginal bleeding, no history of radiation therapy or chemotherapy of the pelvis or the whole body, no history of cancer, no history of infertility, no history of premature ejaculation or impotence. , not having sexual problems in relationship with your spouse, not having vaginal infections, not having psychological disorders such as: psychosis, schizophrenia, delirium, etc., having at least 2 symptoms from the descriptive evaluation table of vaginal mucosa . Obtaining a score of 23 or less according to the sexual function index questionnaire (FSFI), absence of diabetes. The criteria for withdrawal from the study during the research include: sensitivity to cumin vaginal cream, consumption of any drug that affects sexual function during the study, starting to take hormonal drugs during the research, experience of unfortunate or stressful events in the woman or her husband,

Intervention groups
Cumin vaginal cream 5% is used in the amount (one gram) of one fifth of the applicator for eight weeks (six weeks every night and the next two weeks every other night).

Main outcome variables
Vaginal atrophy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220926056043N1**
Registration date: **2022-09-30, 1401/07/08**
Registration timing: **prospective**

Last update: **2022-09-30, 1401/07/08**
Update count: **0**

Registration date
2022-09-30, 1401/07/08

Registrant information

Name
Fatemeh Kermani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 770 1543

Email address
fatemekermani835@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cumin Vaginal Cream on Vaginal Atrophy, Sexual Function Index and Sexual Distress in Postmenopausal Women, Gonanbad –2022

Public title

The Effect of Cumin Vaginal Cream on Vaginal Atrophy, Sexual Function Index and Sexual Distress in Postmenopausal Women, Gonanbad –2022

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 45 and 65 years 1 to 2 years have passed since menopause Having at least a degree with reading and writing literacy Having informed consent to participate in the research Married and monogamous No history of pelvic surgery (according to the participant's statement) Non-use of drugs and alcohol in the woman and her husband (according to the participant's statement) Not taking estrogenic drugs Absence of vaginal bleeding No history of radiation therapy or chemotherapy of the pelvis or the whole body No cancer No history of infertility (according to the participant's statement) Absence of spouse suffering from premature ejaculation or impotence (according to the participant's statement) Absence of vaginal infections (based on the participants' statements and questions about the clinical symptoms of vaginitis) Not suffering from psychological disorders such as: psychosis, schizophrenia, delusions, etc. (according to the participant himself) Having at least 2 symptoms from the descriptive evaluation table of the vaginal mucosa (color, roughness, petechiae, elasticity, dryness) Obtaining a score of 23 or less according to the Sexual Performance Index (FSFI) questionnaire Not having diabetes (according to the participant's statement)

Exclusion criteria:

Allergy to cumin vaginal cream Taking any medication affecting sexual performance during the study Starting to take hormonal drugs during the study Experiencing unfortunate or stressful events in a woman or her husband Dissatisfaction to continue cooperation in research Absence of diseases in women or their spouses that affect sexual performance (such as premature ejaculation, cardiovascular, mental, thyroid and cancers) Getting stressed (such as divorce, infidelity of a spouse, death of loved ones in the last year, serious illnesses or imprisonment)

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

After sampling by available method, randomization is done by block randomization method. The size of all blocks is equal (8 pieces). And in each block (one in the middle) 4 participants will receive vaginal cream with code A and 4 participants will receive vaginal cream with code B (researcher, participant and analyst are unaware of the contents of the creams)

Blinding (investigator's opinion)

Triple blinded

Blinding description

After making the cream and placebo by Mashhad pharmacology specialist, the creams are poured into the tubes coded A and B, and the researcher, participant, analyst will be unaware of the content of the creams.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Imam Khomeini, Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2022-09-26, 1401/07/04

Ethics committee reference number

IR.GMU.REC.1401.067

Health conditions studied

1

Description of health condition studied

Vaginal atrophy

ICD-10 code
N95.2
ICD-10 code description
Postmenopausal atrophic vaginitis

Primary outcomes

1

Description
Vaginal atrophy
Timepoint
Before, 4 and 8 weeks after the intervention
Method of measurement
Descriptive assessment of vaginal mucosa

2

Description
sexual function
Timepoint
Before, 4 and 8 weeks after the intervention
Method of measurement
Female Sexual Function Index

3

Description
Women's sexual distress
Timepoint
Before, 4 and 8 weeks after the intervention
Method of measurement
Female Sexual Distress Scal

4

Description
Vaginal atrophy daily effects
Timepoint
Before, 4 and 8 weeks after the intervention
Method of measurement
Vaginal atrophy daily effects questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The control group used one-fifth of an applicator (one gram) of vaginal cream every night for six weeks and in the next two weeks every other night. At the end of the 4th and 8th week, follow-up will be done again, including clinical examination and filling in the questionnaires of women's sexual function index, the questionnaire of daily effects of vaginal atrophy and the questionnaire of women's sexual distress.
Category
Placebo

2

Description
Intervention group: The intervention group used one-fifth of an applicator (one gram) of vaginal cream every night for six weeks and in the next two weeks every other night. At the end of the 4th and 8th week, follow-up will be done again, including clinical examination and filling in the questionnaires of women's sexual function index, the questionnaire of daily effects of vaginal atrophy and the questionnaire of women's sexual distress.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive health centers in Gonabad
Full name of responsible person
Fatemeh kermani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Postgraduate education expert
Street address
Gonabad University of Medical Sciences, Imam Khomeini, Gonabad
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Email
info@gmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad University of Medical Sciences

Proportion provided by this source

30

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

Gonabad University of Medical Sciences

Full name of responsible person

Fatemeh kermani

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Narjes bahri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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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 participants are coded to increase access to them and their information, and at the time of publication, only the main result is published, and the information of the participants is not published in any way.

When the data will become available and for how long

Six months after the results are published

To whom data/document is available

Access is open to the public.

Under which criteria data/document could be used

If a person has a request, without mentioning the coding of the information in a confidential manner, without the personal information of the person, only the main and secondary results will be provided to the requester.

From where data/document is obtainable

Gmail

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

First, the applicant should send a message to the e-mail and state the reason for using the data. And within a week, the information will be sent to the applicant with conditions and restrictions.

Comments