

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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Email address

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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	- Investigator - Outcome assessor - Data analyser - Data and Safety Monitoring Board
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	Sample size Target sample size: 84
Public title The Effect of Cumin Vaginal Cream on Vaginal Atrophy, Sexual Function Index and Sexual Distress in Postmenopausal Women, Gonanbad -2022	Randomization (investigator's opinion) Randomized
Purpose Treatment	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)
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)	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
Age From 45 years old to 65 years old	Health conditions studied 1 Description of health condition studied Vaginal atrophy
Gender Female	
Phase 3	
Groups that have been masked - Participant - Care provider	

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

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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
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
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Fateme kermani
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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