Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effectiveness of vaginal cream (An Iranian Traditional Medicine product) on subjective symptoms of vulvovaginal atrophy in women with breast cancer

Protocol summary

Study aim

Evaluating the effectiveness of vaginal cream (An Iranian Traditional Medicine product) on subjective symptoms of vulvovaginal atrophy in women with breast cancer referred to Oncology-Radiotherapy Clinic of Shohadaye Tajrish hospital

Design

A clinical trial, before and after, on a group of 50 patients

Settings and conduct

We will evaluate the subjective symptoms of vulvovaginal atrophy (itching, burning, dryness, dyspareunia) at baseline (before intervention), second and fourth weeks of intervention and two and four weeks after the intervention completion, the female sexual function index (sexual desire, sexual arousal, vaginal lubrication, orgasm, sexual satisfaction, sexual pain) were also included at baseline and 4 weeks after initiating the intervention (at intervention completion). Study location: Oncology-Radiotherapy Clinic of Shohadaye Tajrish hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a patient's consent to participate in the project, Ability to fill out forms and questionnaires alone or with the help of a researcher, Age 18 years or older, Married, Menopause, History of breast cancer, Hormonal treatment history, Having subjective symptoms of vulvovaginal atrophy (itching, burning, dryness, dyspareunia) with a minimal sum score of 3; Exclusion criteria: Having multiple sex partners, Acute psychiatric illness and antidepressant use during the last month, Other cancers at the same time as breast cancer, Incomplete chemotherapy and radiotherapy, Use of lubricant or vaginal moisturizer and other vaginal medications during the last month, Not having a negative Pap smear over the last year

Intervention groups

Vaginal cream (An Iranian Traditional Medicine product) recipients

Main outcome variables

Vulvovaginal atrophy subjective symptoms score; itching score; burning score; dryness score; dyspareunia score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191210045687N1**
Registration date: **2020-02-12, 1398/11/23**
Registration timing: **prospective**

Last update: **2020-02-12, 1398/11/23**
Update count: **0**

Registration date

2020-02-12, 1398/11/23

Registrant information

Name

Maryam Radmanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

m.radmanesh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-15, 1398/11/26

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of vaginal cream (An Iranian Traditional Medicine product) on subjective symptoms of vulvovaginal atrophy in women with breast cancer

Public title

Evaluating the effectiveness of the traditional vaginal product on vulvovaginal atrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a patient's consent to participate in the project Ability to fill out forms and questionnaires alone or with the help of a researcher 18 years or older Married Menopause History of breast cancer Hormonal treatment history Having subjective symptoms of vulvovaginal atrophy (itching, burning, dryness, dyspareunia) with a minimal sum score of 3

Exclusion criteria:

Having multiple sex partners Acute psychiatric illness and antidepressant use during the last month Other cancers at the same time as breast cancer Incomplete chemotherapy and radiotherapy Use of lubricant or vaginal moisturizer and other vaginal medications during the last month Not having a negative Pap smear over the last year

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

3th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

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Province

Tehran

Postal code

1985717443

Approval date

2019-12-01, 1398/09/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.437

Health conditions studied

1

Description of health condition studied

Vulvovaginal atrophy

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

Subjective Symptom Score of Vulvovaginal Atrophy Based on Vulvovaginal Subjective Symptom Score Form from 3 to 16

Timepoint

Evaluation of subjective symptoms of vulvovaginal atrophy at baseline (before intervention), 2 and 4 weeks after the intervention beginning, 2 and 4 weeks after the intervention completion

Method of measurement

Vulvovaginal Subjective Symptom Score Form

2

Description

Vulvovaginal Dryness Score Based on Vulvovaginal Subjective Symptom Score Form from 1 to 4

Timepoint

Evaluation of vulvovaginal dryness at baseline (before intervention), 2 and 4 weeks after the intervention beginning, 2 and 4 weeks after the intervention completion

Method of measurement

Vulvovaginal Subjective Symptom Score Form

3

Description
Vulvovaginal Itching Score Based on Vulvovaginal Subjective Symptom Score Form from 1 to 4
Timepoint
Evaluation of vulvovaginal Itching at baseline (before intervention), 2 and 4 weeks after the intervention beginning, 2 and 4 weeks after the intervention completion
Method of measurement
Vulvovaginal Subjective Symptom Score Form

4

Description
Vulvovaginal burning Score Based on Vulvovaginal Subjective Symptom Score Form from 1 to 4
Timepoint
Evaluation of vulvovaginal burning at baseline (before intervention), 2 and 4 weeks after the intervention beginning, 2 and 4 weeks after the intervention completion
Method of measurement
Vulvovaginal Subjective Symptom Score Form

5

Description
Dyspareunia Score Based on Vulvovaginal Subjective Symptom Score Form from 1 to 4
Timepoint
Evaluation of dyspareunia at baseline (before intervention), 2 and 4 weeks after the intervention beginning, 2 and 4 weeks after the intervention completion
Method of measurement
Vulvovaginal Subjective Symptom Score Form

Secondary outcomes

1

Description
Female Sexual Function Index Score
Timepoint
At the beginning of the study (before intervention) and 4 weeks after the intervention (Intervention completion)
Method of measurement
Female Sexual Function Index Questionnaire

2

Description
Sexual desire score
Timepoint
At the beginning of the study (before intervention) and 4 weeks after the intervention (Intervention completion)
Method of measurement
Female Sexual Function Index Questionnaire

3

Description
Sexual arousal score
Timepoint
At the beginning of the study (before intervention) and 4 weeks after the intervention (Intervention completion)
Method of measurement
Female Sexual Function Index Questionnaire

4

Description
Vaginal lubrication score
Timepoint
At the beginning of the study (before intervention) and 4 weeks after the intervention (Intervention completion)
Method of measurement
Female Sexual Function Index Questionnaire

5

Description
Orgasm score
Timepoint
At the beginning of the study (before intervention) and 4 weeks after the intervention (Intervention completion)
Method of measurement
Female Sexual Function Index Questionnaire

6

Description
Sexual satisfaction score
Timepoint
At the beginning of the study (before intervention) and 4 weeks after the intervention (Intervention completion)
Method of measurement
Female Sexual Function Index Questionnaire

7

Description
Sexual pain score
Timepoint
At the beginning of the study (before intervention) and 4 weeks after the intervention (Intervention completion)
Method of measurement
Female Sexual Function Index Questionnaire

8

Description
Satisfaction of treatment
Timepoint
After the Intervention completion
Method of measurement
Asking the patient

Intervention groups

1

Description
Intervention group: Use Vaginal Cream (Traditional Iranian Medicine Product) Contains Chicken Oil and Honey Wax, One applicator every other night for 2 weeks followed by one applicator two nights a week for 2 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Oncology-Radiotherapy Clinic of Shohadaye Tajrish hospital

Full name of responsible person
Maryam Radmanesh

Street address
No. 8, Shams Alley (across from Tavanir), Vali-e- Asr Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Afshin Zarghi

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Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Maryam Radmanesh

Position
MD, PhD Candidate

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Contact

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Publication of results in the form of a Ph.D. thesis and an ISI paper
When the data will become available and for how long
After Ph.D. thesis defense
To whom data/document is available
Public
Under which criteria data/document could be used
For research reasons
From where data/document is obtainable
Shahid Beheshti University of Medical Sciences
What processes are involved for a request to access data/document
Confirmation of responsible person
Comments