

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

Tehran

##### 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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1516745811

**Phone**

+98 21 8877 3521

**Email**

m.radmanesh@sbm.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Zarghi

**Street address**

5th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2243 9780

**Email**

Mpajouhesh@sbm.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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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m.radmanesh@sbmu.ac.ir

**Person responsible for updating data****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

**Street address**

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**Postal code**

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**Phone**

0098 88773521

**Email**

m.radmanesh@sbmu.ac.ir

**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**