

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation of the effects of a lotion containing *Althaea officinalis*, *Ocimum basilicum*, and *Apium graveolens* extracts in the prevention and treatment of radiation therapy-induced dermatitis in breast cancer patients: A Placebo-Controlled, Double-Blind, Randomized Clinical Trial

#### Protocol summary

##### Study aim

A double-blind, randomized, controlled clinical study to investigate the effects of herbal lotion for the prevention and treatment of dermatitis caused by radiation therapy in breast cancer patients

##### Design

The sample size for each group was 34 cases, and in general, the total sample size was equal to 68. Considering a 10% dropout the final sample volume for this study was 74 samples in general.

##### Settings and conduct

Patients referred to the radio-oncology department suffering from breast cancer were included in the study and randomly divided into intervention and control groups. From the first dose of radiation therapy: In the intervention group, standardized herbal lotions are applied topically on the dermatitis-affected area 2 times a day at least two hours before and after radiation therapy.

##### Participants/Inclusion and exclusion criteria

Female over 18 years old and up to 70 years old with breast cancer who underwent a lumpectomy Patients subjected to radiation therapy suffered from dermatitis with an RTOG score equal to 2.5 ( $\pm 0.5$ ).

##### Intervention groups

standardized herbal lotions for topical application on the dermatitis-affected area 2 times a day at least two hours before and after radiation therapy.

##### Main outcome variables

The severity of acute dermatitis caused by radiotherapy as the primary outcome (RTOG questionnaire) The severity of dermatitis symptoms: intensity of pain, intensity of itching, and intensity of burning (RISRAS questionnaire) Duration of dermatitis treatment The time interval until the onset of dermatitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160131026282N2**

Registration date: **2023-09-14, 1402/06/23**

Registration timing: **prospective**

Last update: **2023-09-14, 1402/06/23**

Update count: **0**

##### Registration date

2023-09-14, 1402/06/23

##### Registrant information

##### Name

Behjat Javadi

##### Name of organization / entity

Department of Traditional Pharmacy, School of Pharmacy, Mashhad University of Medical Sciences, Mash

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3882 3255

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2025-02-19, 1403/12/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effects of a lotion containing *Althaea officinalis*, *Ocimum basilicum*, and *Apium graveolens* extracts in the prevention and treatment of radiation therapy-induced dermatitis in breast cancer patients: A Placebo-Controlled, Double-Blind, Randomized Clinical Trial

**Public title**

Evaluation of the effects of a lotion containing *Althaea officinalis*, *Ocimum basilicum*, and *Apium graveolens* extracts in the prevention and treatment of radiation therapy-induced dermatitis in breast cancer patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients (women) >18 years, undergone breast Lumpectomy surgery for breast cancer and a fractionation regimen of at least 42 Gy. Patients capable of finishing radiotherapy and contributing to the research team. The patient is personally capable of lotion application and learning the research instructions. Patient who have not undergone radiotherapy previously.

**Exclusion criteria:**

Patients with ulcers or unhealed wounds, burns, infections, and previous skin complications at the radiotherapy site. Patients who undergo chemotherapy or hormone therapy (adjuvant or neoadjuvant) at the same time Using skin medicines to treat skin diseases other than dermatitis caused by radiation therapy Patients taking high-dose non-steroidal anti-inflammatory drugs. Presence of connective tissue disorders or collagen disorders Allergy to the herbs used in the intervention lotion or any of the components of the formulation Allergy to the routine treatment used in the treatment of dermatitis underlying disease such as diabetes Smoking Taking radiation sensitizing drugs

**Age**

From **18 years** old to **70 years** old

**Gender**

Female

**Phase**

0

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done by a simple method using random numbers created by computer software. By considering the numbers for two groups, randomization is done. For

blinding, the patient will receive the drug (intervention or comparison group) in sealed envelopes that are coded. Coding is done by one of the colleagues of the project and the doctor, evaluator, and patient are blinded.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The number of letter envelopes is recorded with an aluminum wrapper (in order to make the contents of the envelopes unclear). Each of the randomly created sequences is recorded on a card, and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. The patient receives the medication (intervention or control group) in sealed envelopes that are coded. Coding is done by one of the colleagues of the project and the doctor, evaluator, and patient are blinded

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The ethics committee of Mashhad University of Medical Sciences

**Street address**

School of Pharmacy, Pardis University Campus ,Azadi Square, Mashhad

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**Province**

Razavi Khorasan

**Postal code**

9177948954

**Approval date**

2022-08-27, 1401/06/05

**Ethics committee reference number**

IR.MUMS.REC.1401.180

**Health conditions studied****1****Description of health condition studied**

Radiation therapy-induced dermatitis in breast cancer patients

**ICD-10 code**

L58

**ICD-10 code description**

Radiodermatitis

**Primary outcomes****1****Description**

The severity of the radiation therapy-induced dermatitis

**Timepoint**

At the baseline and after 2, 4 and 6 weeks

**Method of measurement**

RTOG/EORTC toxicity criteria

**2****Description**

Evaluating the severity of dermatitis symptoms (level of pain, itchiness and burning as well as the effect on day to day life)

**Timepoint**

At the baseline and after 2, 4 and 6 weeks

**Method of measurement**

The radiation-induced skin reaction assessment scale (RISRAS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: A standardized herbal lotion is applied on the affected area twice a day at least 2 hours before and after radiation therapy. The patients are requested not to wear cloth before 10 min of lotion application and not to wash a area at least for 2 hours. The lotion is administered from the first day of radiation therapy to 2 weeks after the end of the therapy (for 6 weeks).

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Radiology oncology ward, Omid Hospital, Mashhad University of Medical Sciences

**Full name of responsible person**

Behjat Javadi

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Alandasht Square, Koohsangi Avenue, Mashhad, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vice Chancellor of Research of Mashhad University of Medical Sciences

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Ghorashi Building, University Street, Mashhad, Iran

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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**

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**

Behjat

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Assistant professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Mashhad University of Medical Sciences  
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Assistant professor

**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No other information is 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

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

The details will be included in the article.

### When the data will become available and for how long

After publishing the data as an article

### To whom data/document is available

No limitations

### Under which criteria data/document could be used

No limitations

### From where data/document is obtainable

Dr. Behjat Javadi

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

Email request

### Comments