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 graveolensin 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 (±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

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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 graveolensin 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 graveolensin 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
City
Mashhad
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 firs 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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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

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Person responsible for updating data

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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