Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of a combined topical formulation of Plantago major leafs and Rosa damascena oil on prevention of acute radiation dermatitis in breast cancer patients- A randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim
Determining the effect of a combined topical formulation of Plantago major leafs and Rosa damascena oil on prevention of acute radiation dermatitis in breast cancer patients

Design
A randomized, double-blind, parallel-design controlled clinical trial in 100 breast cancer patients

Settings and conduct
The study site is the Radiation Therapy Center of Namazi Hospital, Shiraz. Blinding will be provided to patients and the evaluating medical staff. The treatment duration is 7 weeks. Patients will be followed up and visited weekly for the duration of radiation therapy and two weeks after the last radiation therapy session.

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients (≥18 years) with a confirmed diagnosis of breast cancer who require external radiotherapy. Exclusion criteria:: 1-Prior chest wall radiation 2-Skin tumors, rashes, ulcers, or unhealed scars in the radiation field 3-Hx of connective tissue disease 4-Hx of diabetes 5-Concomitant use of chemotherapy

Intervention groups
100 eligible patients will be randomly assigned to two groups. The intervention group will receive a topical formulation of Plantago major and rose-oil, and the control group will receive a placebo. Patients in both groups will be instructed to cover the area under radiation with a thin layer of topical agent twice a day from the first day of radiotherapy until two weeks after the final session.

Main outcome variables
Reducing the incidence & severity of acute radiation-induced dermatitis in patients with breast cancer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150830023823N5**
Registration date: **2026-01-09, 1404/10/19**
Registration timing: **prospective**

Last update: **2026-01-09, 1404/10/19**
Update count: **0**

Registration date
2026-01-09, 1404/10/19

Registrant information

Name
Ali Tavakoli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3233 1028

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2026-09-22, 1405/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of a combined topical formulation of Plantago major leafs and Rosa damascena oil on prevention of acute radiation dermatitis in breast cancer patients- A randomized double-blind placebo-controlled clinical trial

Public title
Effect of a combined topical formulation of Plantago major leafs and Rosa damascena oil on prevention of acute radiation dermatitis in breast cancer patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with a definitive diagnosis of breast cancer who have undergone quadrantectomy and are scheduled to receive a course of external radiotherapy to the chest wall 18 years old and more

Exclusion criteria:
Previous history of radiotherapy to the chest wall A skin tumor, rash, ulcer, or unhealed scar in the area under radiation History of connective tissue disorders History of diabetes mellitus Concomitant use of chemotherapy

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization In this study, we use permutation block randomization method with blocks of size 4 and an allocation ratio of 1:1. Since we have two interventions, labeled A and B, each block consist of one of the six possible four-tuple permutations of A and B. The different permutations are assigned to the numbers 1 to 6 as follows: 1 – AABB 2 – ABAB 3 – ABBA 4 – BBAA 5 – BABA 6 – BAAB Using a random number table, we extract numbers sequentially. Whenever a number between 1 and 6 appears, the corresponding block assigned to that number is selected. If the numbers 0, 7, 8, or 9 appear, they are ignored. We need 25 blocks of size 4 according to the sample size (100 subjects). Therefore, we continue this process until a list of 100 random sequences is generated. Finally, based on this random list, 50 patients will be allocated to group A and 50 patients to group B.

Blinding (investigator's opinion)
Double blinded

Blinding description
The placebo is made to be similar in color, odor, packaging, and other characteristics to the Combined Topical Formulation of Plantago major leafs and Rosa damascena Oil so that patients and researchers cannot distinguish between them.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz Medical School

Street address
Zand St.

City
shiraz

Province
Fars

Postal code
7134845794

Approval date
2025-12-20, 1404/09/29

Ethics committee reference number
IR.SUMS.MED.REC.1404.518

Health conditions studied

1

Description of health condition studied
Acute radiodermatitis

ICD-10 code
L58.0

ICD-10 code description
Acute radiodermatitis

Primary outcomes

1

Description
Incidence and the severity of dermatitis

Timepoint
weekly for 7 week

Method of measurement
Physician observation with Common Terminology criteria for Adverse Events (CTCAE) version 6

Secondary outcomes

1

Description
Burning sensation grade
Timepoint
Weekly
Method of measurement
Questioning the patient with the Patient Symptom Scale

2

Description
Pain severity
Timepoint
Weekly
Method of measurement
Questioning the patient with the Patient Symptom Scale

3

Description
Pruritus severity
Timepoint
Weekly
Method of measurement
Questioning the patient with the Patient Symptom Scale

Intervention groups

1

Description
Intervention group:The drug of the intervention group is a combined topical formulation of Plantago major leafs extract and Rosa damascena oil that is made by the Knowledge-Based Pharmaceutical Chemists Company (Daneshkim) in Shiraz, and is then sent to the laboratory of the Faculty of Pharmacy for microbial control and chemical evaluation tests. Patients will be instructed to cover the skin of the radiation-treated area with a thin layer of the topical formulation twice daily (morning and evening). The duration of use is 7 weeks, starting on the first day of radiation therapy and continuing until two weeks after the last radiation therapy session. To reduce the bolus effect, it is recommended that there be at least a two-hour interval between the use of the topical formulation and the start of the radiotherapy session. Patients are also urged to avoid the use of other topical compounds during treatment.
Category
Prevention

2

Description
Control group: The placebo is prepared with the same materials used to make the drug except for the Plantago major leafs extract and Rosa damascena oil. The placebo is also made by the Knowledge-Based Pharmaceutical Chemists Company (Danshkim) in Shiraz. Patients will be instructed to cover the skin of the radiation-treated area with a thin layer of the topical formulation(placebo) twice daily (morning and evening). The duration of use is 7 weeks, starting on the first day of radiation therapy and continuing until two weeks after the last radiation therapy session. To reduce the bolus effect, it is recommended that there be at least a two-hour interval between the use of the formulation and the start of the radiotherapy session. Patients are also urged to avoid the use of other topical compounds during treatment.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiotherapy department in Namazi Hospital، Shiraz
Full name of responsible person
Mahvash Ranjbar
Street address
Zand St، Medical School، Seventh floor، Persian Medicine Department
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Aytack13@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
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7134814336
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+98 71 3212 2430
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vcrdep@sums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Ali Tavakoli
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Assistant Professor
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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
for privacy
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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