Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of a combination herbal ointment (pomegranate peel, alum, honey, and oak apple) on the prevention of radiation-induced dermatitis during adjuvant radiation in patients with breast cancer after conservative breast surgery: A randomized controlled trial

Protocol summary

Study aim

Efficacy of a combination herbal ointment (pomegranate peel, alum, honey, and oak apple) on the prevention of radiation-induced dermatitis during adjuvant radiation in patients with breast cancer after conservative breast surgery

Design

A controlled clinical trial with a parallel groups , double-blind, randomized, phase 2 on 100 patients. Random allocation software was used for randomization

Settings and conduct

It was conducted on under radiotherapy breast-cancer patients In Namazi Hospital in Shiraz

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with breast cancer confirmed by pathology, Breast-conserving surgery with or without lymph node dissection, The average time interval between chemotherapy and radiation therapy is 3-4 weeks*** Exclusion criteria: prior radiotherapy, Concurrent chemotherapy, skin involvement, connective tissue disease, diabetes nor chronic kidney disease, rash, ulcer or skin infection in the site of radiation, systemic infection, Existing nonhealing scar in the site of radiation, concomitant local treatment, cigarette nor drugs addiction, Patient unwillingness to participate in the study

Intervention groups

Intervention group: drug use starts from the first radiotherapy session. It is applied twice a day with a thickness of 1 to 2 mm, at least 6 hours apart, on the radiation surface, the limits of which are determined by the treatment design. Due to the possibility of creating a bolus effect, patients are advised to use the ointment at least 4 hours before radiotherapy and to use the ointment for a week after the completion of radiotherapy. Placebo group: The use of a placebo starts from the first radiotherapy session. It is applied twice a day, at least 6 hours apart, with a thickness of 1 to 2 mm on the radiation surface, whose limits are determined by the treatment design.

Main outcome variables

Grade of radiation dermatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220904055879N1**
Registration date: **2022-12-10, 1401/09/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-10, 1401/09/19**
Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name

Shakiba Javadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5337

Email address

shakibaa89@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of a combination herbal ointment (pomegranate peel, alum, honey, and oak apple) on the prevention of radiation-induced dermatitis during adjuvant radiation in patients with breast cancer after conservative breast surgery: A randomized controlled trial

Public title

Efficacy of a combination herbal ointment on the prevention of radiation burning in breast cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pathology of breast cancer Breast conserving surgery with or without lymph node dissection The average time interval between chemotherapy and radiation therapy is 3-4 weeks

Exclusion criteria:

prior radiotherapy prior chemotherapy skin involvement connective tissue disease diabetes nor chronic kidney disease rash, ulcer or skin infection in the site of radiation systemic infection Existing nonhealing scar in the site of radiation concomitant local treatment cigarette or drugs addiction Patient unwillingness to participate in the study

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization allocation is done based on the permutation block table obtained from the Random allocation software (Version 1.00, Isfahan University of Medical Sciences, Iran). For this purpose, blocks of four are used. For this purpose, patients are randomly divided into two drugs (A) and placebo (B) groups. Dark-colored envelopes are used to allocate concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient, the treatment team, and the clinical assessor are blinded. For this purpose, the drug and the placebo are made in the same color and smell and are packed in the same containers. To name the drug, letters (A) are used for the drug and (B) for the placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

esearch Ethics Committees of School of Medicine - Shiraz University of Medical Sciences

Street address

Radiotherapy ward.,Namazi hospital., Namazi Sq., Shiraz

City

Shiraz

Province

Fars

Postal code

7193711351

Approval date

2022-05-14, 1401/02/24

Ethics committee reference number

IR.SUMS.MED.REC.1401.097

Health conditions studied

1

Description of health condition studied

radiation dermatitis

ICD-10 code

L59.0

ICD-10 code description

Erythema ab igne [dermatitis ab igne]

Primary outcomes

1

Description

Dermatitis Grade

Timepoint

Weekly

Method of measurement

inspection

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of the Compound herbal remedy including the extracts of pomegranate peel, alum, honey, and oak apple starts from the first radiotherapy session. It is applied twice a day with a thickness of 1 to 2 mm, at least 6 hours apart, on the radiation surface, the limits of which are determined by the treatment design. Due to the possibility of creating a bolus effect, patients are advised to use the ointment at least 4 hours before radiotherapy and to use the ointment for a week after the completion of radiotherapy. The compound traditional medicine related drug is made by the pharmacist.

Category

Treatment - Drugs

2

Description

Placebo group: The use of a placebo starts from the first session of radiotherapy. It is applied twice a day, at least 6 hours apart, with a thickness of 1 to 2 mm on the radiation surface, whose limits are determined by the treatment design. Due to the possibility of creating a bolus effect, patients are advised to use the ointment at least 4 hours before radiotherapy and to use the ointment for a week after the completion of radiotherapy. The placebo is made by the pharmacist.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi hospital
Full name of responsible person
Shakiba Javadi
Street address
Radiotherapy ward., Namazi hospital., Namazi Sq.
City
Shiraz
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7193711351
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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zand street
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7134814336
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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
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
Shakiba Javadi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Radiotherapy ward. Namazi hospital
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Parvizi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available