Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of the traditional medicinal product of Rosa damascene in prevention of radiodermatitis in patients with breast cancer

Protocol summary

Study aim
Determining the effect of rose extract in prevention of radiodermatitis in patients with breast cancer

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients.

Settings and conduct
The study will be conducted in the radiation oncology department of Namazi Hospital affiliated to Shiraz University of Medical Sciences. Participants in both groups were requested to apply the coded container to the desired area once a day for 5 weeks. This process will be implemented for both the intervention and placebo groups for up to 5 weeks, and every week before the start of radiation therapy, the skin of the radiation treatment area in both the intervention and placebo groups will be examined by the researcher and based on the CTCAE v5.0 checklist for dermatitis.

Participants/Inclusion and exclusion criteria
Entry criteria: Women over 18 years of age with a histologically confirmed diagnosis of breast cancer who are candidates for radiation therapy after breast surgery Criteria for not entering the study: - Inflammatory or metastatic breast cancer - Severe infection requiring antibiotic treatment - History of previous radiation therapy for breast cancer - Lack of consent to participate in the study Exclusion criteria: - Failure to use rose oil according to instructions by patients - Events such as reaction or increased sensitivity to rose oil - Severe burns in the treated area

Intervention groups
Intervention group: the product containing rosehip extract in olive oil base will be given to patients and they will be requested to apply to the desired area once a day for 5 weeks. Control group: patients of the placebo group, the product containing olive oil.

Main outcome variables
Dermatitis based on CTCAE grading to evaluate the side effects of radiation therapy on the skin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241006063271N1**
Registration date: **2024-10-09, 1403/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-09, 1403/07/18**
Update count: **0**

Registration date
2024-10-09, 1403/07/18

Registrant information

Name
Mozhdeh Sanei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3626 9094

Email address
sanei_m@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-06, 1403/07/15

Expected recruitment end date
2026-02-04, 1404/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of the traditional medicinal product of Rosa damascene in prevention of radiodermatitis in patients with breast cancer

Public title
Investigating the effect of Rosa damascene extract on burns caused by radiation therapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Women with breast cancer confirmed by histology which are candidates for radiation therapy
Exclusion criteria:
Inflammatory or metastatic breast cancer Severe infection requiring antibiotic treatment History of previous radiation therapy for breast cancer Diabetes Inflammatory skin disorders Connective tissue disorders Simultaneous use of non-steroidal anti-inflammatory drugs Simultaneous use of corticosteroids and other drugs that suppress the immune system or antioxidants. The presence of any wounds, scars, burns and any other previous skin damage at the radiation therapy site Patients with allergy or hypersensitivity to intervention ingredients
Age
From **18 years** old
Gender
Female

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to one of the two study groups with 1:1 blocks using a random number table (by https://www.random.org).
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug in both the intervention and placebo groups will have the same form and will have a code that another person (other than the people involved in the study) is aware of. Also, the evaluator is not aware of the codes and type of substance available, and based on the code on the drug, they record their evaluation results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Ethics Committee in Research, Research and Technology Deputy, Shiraz University of Medical Sciences Central Building, 7th Floor, Zand Street
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2024-10-05, 1403/07/14
Ethics committee reference number
IR.SUMS.MED.REC.1403.461

Health conditions studied

1

Description of health condition studied
Dermatitis caused by radiotherapy
ICD-10 code
L58
ICD-10 code description
Radiodermatitis

Primary outcomes

1

Description
Dermatitis based on CTCAE grading to evaluate the side effects of radiation therapy on the skin
Timepoint
Before starting the intervention, the end of each week for 5 weeks
Method of measurement
CTCAE form version 5 to evaluate skin dermatitis caused by radiation therapy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The product containing rose extract

based on olive oil (prepared by a pharmacist under the supervision of the Faculty of Pharmacy) will be prepared and will be given in 50 ml jars with a coded label, and they are requested to apply to the desired area once a day for 5 weeks.

Category

Prevention

2

Description

Control group: The patients of the placebo group will receive a product containing olive oil (based on the original product - without rosehip extract), which is packaged in the same containers (in 50 ml jars) as the intervention group, with a coded label, and they will be requested to apply to the desired once a day for 5 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi hospital

Full name of responsible person
Mozhdeh Sanei

Street address
Namazi hospital, Zand st., Namazi sq.

City
Shiraz

Province
Fars

Postal code
7193613311

Phone
+98 71 3612 5000

Email
Nemazee_inf@sums.ac.ir

Web page address
https://namazi.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Hashem Hashempour

Street address
Research and Technology Deputy, Shiraz University of Medical Sciences Central Building, 7th Floor, Zand Street

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7134814336

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hashempurm@sums.ac.ir

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
Mozhdeh Sanei

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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No. 82, 6th alley, Sattarkhan St.

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

Full name of responsible person
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Position
Resident

Latest degree
Medical doctor
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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
There is no further information
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