Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effectiveness of administration of Centella asiatica extract in comparison with placebo on the prevention of radiation-induced dermatitis in breast cancer patients

Protocol summary

Study aim

Comparison of the frequency of grade 2 and higher of dermatitis in intervention and placebo groups Comparison of mean severity of dermatitis in intervention and placebo groups Comparison of the mean onset time of dermatitis in intervention and placebo groups Comparison of the frequency of radiotherapy discontinuation due to dermatitis in intervention and placebo groups Comparison of the frequency of dermatitis in intervention and placebo groups

Design

A single center double-blind, randomized, parallel-group clinical trial

Settings and conduct

There is no standard treatment for the prevention and treatment of radiotherapy-induced dermatitis. This clinical trial aim to compare the effectiveness of Centella asiatica extract with placebo in the prevention of radiation-induced dermatitis in breast cancer patients referred to the oncology radiotherapy ward of Namazi Hospital. In this study, participants, clinician, researcher, and outcome assessor will be blind to the study groups.

Participants/Inclusion and exclusion criteria

The study population will include patients with breast cancer if the inclusion criteria such as newly diagnosed disease and the indication for adjuvant radiotherapy includes breast conserving surgery or the presence of a tumor larger than 5 cm or lymph node involvement in the patient underwent modified mastectomy present. Conditions for non-entry of participants including not giving the consent to participate, history of radiation therapy of the breast and chest, history of connective tissue disease and the presence of metastases.

Intervention groups

Patients with breast cancer who are candidates for adjuvant radiotherapy will receive Centella Asiatica extract or placebo from the start of treatment.

Main outcome variables

Frequency of dermatitis grade two and higher; Mean score of severity of dermatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211231053576N1**
Registration date: **2022-01-18, 1400/10/28**
Registration timing: **prospective**

Last update: **2022-01-18, 1400/10/28**
Update count: **0**

Registration date

2022-01-18, 1400/10/28

Registrant information

Name

Ziba Afshari Aghajari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4332

Email address

ziba.afshar68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of administration of Centella asiatica extract in comparison with placebo on the prevention of radiation-induced dermatitis in breast cancer patients

Public title

Centella asiatica extract on the prevention of radiation-induced dermatitis in breast cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-65 The Karnofsky performance scale more and equal 70 Newly diagnosed breast cancer patients Patients underwent breast conserving surgery A tumor size more than 5 centimeter in patients underwent mastectomy Regional lymph-node involvement in patients underwent mastectomy Conventional radiotherapy regimen

Exclusion criteria:

Not giving consent to participate Pregnancy History of breast and chest radiation therapy History of connective tissue disease such as scleroderma or systemic lupus Distant metastasis at the presentation

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in the present study is simple randomization using a table of random numbers. Online tools will be used to create a random sequence. Allocation will be made using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants, clinician, researcher, and outcome assessor will be blind to the study groups.

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

Zand St., Central Building of Shiraz University of Medical Sciences, 7th Floor, Vice Chancellor for Research and Technology, Secretariat of the Research Ethics Committee

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-12-20, 1400/09/29

Ethics committee reference number

IR.SUMS.MED.REC.1400.510

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Dermatitis

Timepoint

Weekly during the intervention

Method of measurement

Physical examination

Secondary outcomes

1

Description

Radiotherapy leave

Timepoint

Weekly during the intervention

Method of measurement

History taking

Intervention groups

1

Description
Intervention group: During radiation therapy for breast cancer patients, treatment with Centella Asiatica extract (made by Nature Healing Songs Company, Tehran, Iran) will be done. Patients will be asked to apply a topical layer of ointment to the skin daily after treatment in the radiotherapy setting.
Category
Treatment - Drugs

2

Description
Control group: During radiation therapy for breast cancer patients, treatment will be performed with an ointment that is similar in consistency, odor, and color to the intervention group. Patients will be asked to apply a topical layer of ointment to the skin daily after treatment in the radiotherapy setting.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Mansour Ansari
Street address
Radiation Oncology ward, Nemazee Teaching Hospital, Namazi Sq., Zand Ave.
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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
Mahtab Memarpour
Street address
Zand St., the central building of Shiraz University of Medical Sciences, the seventh floor
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Postal code
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Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Web page address
https://research.sums.ac.ir/Page-ResearchM/fa/205
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
Ziba Afshari Aghajari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After the consent of the scientific officer and the approval of the ethics committee, all data is potentially shareable after unidentified individuals.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Study data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The results of this study can be used for pooled meta-analysis.

From where data/document is obtainable
The data can be accessed by correspondence with the scientific officer. Address: Radiation Oncology ward, Nemazee Teaching Hospital, Namazi Sq., Zand Ave. Shiraz, Fars. 7134814336. Iran Phone +98 71 3647 4332 Cellphone +98 921 165 5956 Fax +98 71 3647 4326 E-mail address mehrdadg239@gmail.com

What processes are involved for a request to access data/document
After the consent of the scientific officer and the approval of the ethics committee, all data is potentially shareable after unidentified individuals

Comments