

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.

City

Shiraz

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7193613311

Phone

+98 71 3647 4332

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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

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

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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 scientific inquiries

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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