

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of topical sylimarin formulation efficacy in prevention of radiodermatitis in breast cancer patients

Protocol summary

Summary

Forty patients who are referred to the Imam-Reza hospital affiliated to Mashhad University of Medical Sciences with breast cancer diagnosis according to the histopathology results, with age above 18 years old that underwent mastectomy are included in study. These patients will receive radiotherapy with or without coverage of axillary lymph nodes. The tridimensional therapy plan is used to take total dose of 50.4 Gy (1.8 Gy daily during the course 5.5 weeks). Boost dose 16.9 Gy is radiated to the initial involvement area. Patients randomly are included in silymarin or placebo group and will receive formulation in the chest area under radiotherapy twice daily (about 1g) from the first day of radiotherapy (two hours before the first radiotherapy session) until the end of the treatment course. Patients in both groups are evaluated at the beginning and during radiotherapy, at weekly intervals, in terms of the radiodermatitis occurrence according to the criteria of RTOG and NIH CTCAE version 4.03. Moreover, at weekly intervals, patients will be interviewed regarding possible adverse reactions or new prescribed or OTC medications. It should be noted that the administrators (oncology specialists) are unaware of the type of prescription drug (placebo-drug) and are prepared and numbered by a clinical pharmacist and placebo in similar forms..

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110730760N1**
Registration date: **2017-11-01, 1396/08/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Hediyeh Karbasforooshan

Name of organization / entity

Faculty of pharmacy

Country

Iran (Islamic Republic of)

Phone

+98 51 3866 3516

Email address

karbasfh911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of topical sylimarin formulation efficacy in prevention of radiodermatitis in breast cancer patients

Public title

Evaluation of topical sylimarin formulation efficacy in prevention of radiotherapy induced skin reactions in breast cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age above 18 years; Breast cancer

patients after mastectomy undergoing radiotherapy; X-ray total dose of 50.4 GY Exclusion criteria: Diabetes; Smoking; Anti inflammatory drugs; Immunosuppressor drugs; Immunodeficiency diseases; Connective tissue diseases

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Central organization of Mashhad University of Medical Sciences, Daneshgah Ave.

City

Mashhad

Postal code

1394491388

Approval date

2016-10-24, 1395/08/03

Ethics committee reference number

IR.MUMS.REC.1395.27

Health conditions studied

1

Description of health condition studied

Radiodermatitis

ICD-10 code

L58.9

ICD-10 code description

Radiodermatitis, unspecified

Primary outcomes

1

Description

radiodermatitis occurrence

Timepoint

1 week after intervention,2week after intervention,3week after intervention,4week after intervention,5week afterintervention

Method of measurement

NCI CTCAE version 4.03 and Acute Radiation Morbidity Scoring Criteria (RTOG)

Secondary outcomes

empty

Intervention groups

1

Description

Silymarin ointment produced by Goldaru Company, twice daily on breasts, for 5.5 weeks after radiotherapy

Category

Treatment - Drugs

2

Description

Placebo ointment produced by Goldaru Company, twice daily on breasts, for 5.5 weeks after radiotherapy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Sare Hosseini

Street address

Imam Reza Sq.,Imam Reza Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vakil Abad Blv.- School of Pharmacy

City
Mashhad

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Hedyieh Karbasforooshan

Position
Pharm.D student

Other areas of specialty/work
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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty