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
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Iran (Islamic Republic of)
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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
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Person responsible for updating data

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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