Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Topical Erythropoietin Effectiveness for prophylaxis of radiation induced dermatitis in breast cancer patients

Protocol summary

Study aim
Topical Erythropoietin Effectiveness for prophylaxis of radiation induced dermatitis in breast cancer patients refer to Ramazan Zadeh radiotherapy center of Yazd

Design
A total of 50 female patients older than 18 years with positive histology confirmed the diagnosis of invasive and localized breast cancer, who are candidates for adjuvant radiotherapy after surgery (breast conservation surgery or mastectomy). Patients will be randomized according to a table of random numbers. The study is three-blind and the duration of using the cream is from the first day of radiotherapy to the last day of radiation.

Settings and conduct
This study is a three-blind study that will be performed at Shahid Ramezanzadeh Radiation Therapy Center in Yazd. Patients, Radiation oncologist and evaluator of the outcome of the intervention will be blinded. Using the cream is from the first day of radiation therapy to the last day of radiation therapy twice daily.

Participants/Inclusion and exclusion criteria
A total of 50 female patients older than 18 years with positive histology confirmed the diagnosis of invasive and localized breast cancer, who are candidates for adjuvant radiotherapy after surgery (breast conservation surgery or mastectomy).

Intervention groups
Intervention group: receiving 0.168% Erythropoietin cream Control group: receiving placebo

Main outcome variables
Patients' skin phototype, radiotherapy-induced skin reaction intensity, scaling intensity, worst pain experienced

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240813062742N1**
Registration date: **2024-10-05, 1403/07/14**
Registration timing: **prospective**

Last update: **2024-10-05, 1403/07/14**
Update count: **0**

Registration date
2024-10-05, 1403/07/14

Registrant information

Name
Sahar Mesbah

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3826 3448

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sahar_mesbah@yahoo.com

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2025-03-05, 1403/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Topical Erythropoietin Effectiveness for prophylaxis of radiation induced dermatitis in breast cancer patients

Public title
Topical Erythropoietin Effectiveness for prophylaxis of

radiation induced dermatitis in breast cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients older than 18 years patients with positive histology confirm invasive and localized breast cancer Patients who candidates for adjuvant radiotherapy after surgery (breast conserving or mastectomy) Adequate literacy to fill out a consent form, understand the study, use the drug, report pain and possible side effects

Exclusion criteria:

Inflammatory or metastatic carcinoma Extensive skin diseases Connective tissue diseases known sensitivity to drug

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to select the sample people from the table of the random numbers, the researcher randomly starts from a point of the table in the direction of the row or column. Researcher can close her eyes and choose a point. Then based on whether the number is even or odd, the patient is given medicine A or B.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After the cream preparement , the labels A and B are affixed by a third person and the patients, Radiation oncologist and evaluator of this outcome will be blinded to the type of the intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's Committee of Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of medical Sciences, Shohadaye Gomnam Blvd, Allem square, Yazd, Iran

City

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Province

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Postal code

8915173143

Approval date

2023-07-16, 1402/04/25

Ethics committee reference number

IR.SSU.MEDICINE.REC.1402.135

Health conditions studied

1

Description of health condition studied

Radiodermatitis

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Acute radiation dermatitis

Timepoint

Weekly during radiotherapy and two weeks after the end of radiotherapy

Method of measurement

Based on the Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer (RTOG / EORTC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Topical Erythropoietin cream is made by the operator in the laboratory. Patients with breast cancer referred to the center Radiation therapy is included in the study. Patients apply the cream twice a day from the first day of radiotherapy to the last day on the radiation receiving area and after two hours the area is washed. In case of grade 2 dermatitis, the drug is discontinued and the patient undergoes routine treatments. but remains in the study until the end of treatment for follow-up.

Category

Prevention

2

Description
Control group: Placebo cream is made by the operator in the laboratory. Patients with breast cancer referred to the center Radiation therapy is included in the study. Patients apply the cream twice a day from the first day of radiotherapy to the last day on the radiation receiving area and after two hours the area is washed. In case of grade 3 dermatitis, the drug is discontinued and the patient undergoes routine treatments. but remains in the study until the end of treatment for follow-up.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Ramezanzadeh Radiation Therapy Center

Full name of responsible person
Dr. Massoud Shabani

Street address
Shahid Motahari Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Seyede Sahar Mesbah

Position
University student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available