

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effectiveness and safety of Metformin gel in prevention of acute radiation dermatitis in breast cancer patients (a randomized, double-blind, placebo-controlled clinical trial)

Protocol summary

Study aim

Evaluation of effectiveness and safety of Metformin gel in prevention of acute radiation dermatitis (ADR) in breast cancer patients

Design

This study is a double-blind, randomized, placebo-controlled clinical trial.

Settings and conduct

This study will be performed in the radiotherapy department of Vali'asr Hospital affiliated with ZUMS (Zanjan, Iran). The eligible participants were randomly allocated to receive the metformin gel or placebo. All applications of the gel will be started on day 1 of radiotherapy and continued during and for 4 weeks after the completion of the radiation. The patients will be advised to apply a thin layer of their allocated gel of the area of skin being irradiated, twice a day at least two hours before and after radiotherapy and during radiotherapy, patients were approached to adhere to skincare recommendations of clinical practice guidelines for the prevention of ADR from the MASCC Skin toxicity study group. The patients, researchers, and the radio-oncologists were not aware of the patients' allocated group.

Participants/Inclusion and exclusion criteria

Female patients (age ≥ 18 years) with histologically confirmed localized invasive breast carcinoma who were scheduled to receive at least 50 Grays of adjuvant radiotherapy after breast surgery are included in this study. Patients with a prior history of chest radiotherapy, concurrent chemotherapy (except trastuzumab and hormonal therapy), inflammatory or metastatic breast carcinoma, generalized skin disorders, connective tissue disorders, known hypersensitivity to metformin, or any other excipients of gel are excluded from the study

Intervention groups

Metformin gel Placebo gel

Main outcome variables

ADR; radiotherapy-induced pain; radiotherapy-induced moist desquamation, skin-related quality of life of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211029052907N3**

Registration date: **2022-03-12, 1400/12/21**

Registration timing: **prospective**

Last update: **2022-03-12, 1400/12/21**

Update count: **0**

Registration date

2022-03-12, 1400/12/21

Registrant information

Name

Monireh Maham

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness and safety of Metformin gel in prevention of acute radiation dermatitis in breast cancer patients (a randomized, double-blind, placebo-controlled clinical trial)

Public title
Evaluation of metformin gel effect on prevention of radiation acute dermatitis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
female patients age ≥ 18 years with a histologically confirmed diagnosis of localized invasive breast carcinoma receiving adjuvant radiotherapy at least 50 Gy after breast surgery (breast-conserving surgery or mastectomy)
Exclusion criteria:
Prior history of radiotherapy to the treatment fields
Inflammatory or metastatic breast carcinoma
Concurrent chemotherapy with RT (except trastuzumab and hormonal therapy)
Generalized skin disorder
Connective tissue disorders
Untreated surgical wounds
Known allergy or hypersensitivity history to metformin or any other ingredients of the gel

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned into 2 groups with the help of a computer-generated random assignment by an independent statistician who was not part of the study team. Allocation will be concealed using sequentially numbered opaque sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Eligible participants after signing the informed consent form will be randomly allocated to receive the Metformin gel or the placebo using a computer-generated random number list prepared by an investigator without any clinical involvement. The patient, the researcher, and the

radiation-oncologist were not aware of the patients' allocated gel.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethnic Committees of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi square
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Zanjan
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Zanjan
Postal code
4513956184

Approval date
2022-02-22, 1400/12/03

Ethics committee reference number
IR.ZUMS.REC.1400.509

Health conditions studied

1

Description of health condition studied
Acute radiation dermatitis

ICD-10 code
L58.0

ICD-10 code description
Acute radiodermatitis

Primary outcomes

1

Description
Acute radiation dermatitis

Timepoint
Patients will be evaluated for acute radiation dermatitis severity weekly (after every fifth RT session).

Method of measurement
The severity of acute radiation dermatitis will be scored using the radiation therapy oncology group and the European organization for research and treatment of cancer (RTOG/EORTC) criteria based on the clinical presentation.

Secondary outcomes

1

Description

radiotherapy-induced pain

Timepoint

Patients will be evaluated for radiotherapy-induced pain weekly (after every fifth RT session).

Method of measurement

The worst experienced pain will be evaluated using a visual analog scale weekly.

2

Description

radiotherapy-induced moist desquamation

Timepoint

Patients will be evaluated for radiotherapy-induced moist desquamation weekly (after every fifth RT session).

Method of measurement

The size and severity of moist desquamation will be assessed by the common terminology criteria for adverse events (CTCAE version 5.0) criteria based on the clinical presentation.

3

Description

skin-related quality of life

Timepoint

the patients will be requested to fill out the dermatology life quality index (DLQI) from considering their feelings during the past week.

Method of measurement

The skin-related quality of life of the patients will be appraised using the Dermatology life quality index (DLQI) score.

Intervention groups

1

Description

Intervention group: intervention group will use metformin gel which is made in laboratory, for 2 times a day from the first session of radiotherapy to 4 weeks after the last session. In each time a thin layer of gel will be consumed on the area exposed to the radiation.

Category

Prevention

2

Description

Control group: placebo gel

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Monireh Maham

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

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?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Monireh Maham

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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