Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 24 3347 3635

Email address

m.maham@zums.ac.ir

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

City

Zanjan

Province

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
Street address
Valiasr Hospital, Valiasr square, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0801
Fax
Email
valiasr@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Samad Nadri
Street address
Zanjan University of Medical Sciences, Azadi Square
City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24 3315 6141
Email
research@zums.ac.ir
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

Street address
Pharmacy Faculty, Zanjan University of Medical Sciences, Dr. Soubuti Blvd, Zanjan

City
Zanjan

Province
Zanjan

Postal code
4513956184

Phone
+98 24 3347 3635

Email
m.maham@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Monireh Maham

Position
Assistant professor

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Street address
Pharmacy Faculty, Zanjan University of Medical Sciences, Dr. Soubuti Blvd, Zanjan

City
Zanjan

Province
Zanjan

Postal code
4513956184

Phone
+98 24 3347 3635

Email
m.maham@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Monireh Maham

Position
Assistant Professor

Latest degree
Specialist

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Medical Pharmacy

Street address
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Province
Zanjan

Postal code
4513956184

Phone
+98 24 3347 3635

Email
m.maham@zums.ac.ir

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