Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of effectiveness and safety of montelukast gel in prevention of acute radiation dermatitis in breast cancer patients .

Protocol summary

Study aim
Evaluation of effectiveness and safety of montelukast gel in prevention of acute radiation dermatitis 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 montelukast 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 acute radiation reactions 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 montelukast, or any other excipients of gel are excluded from the study.

Intervention groups
Montelukast gel Placebo gel

Main outcome variables
The primary endpoint is to determine whether the montelukast gel can reduce the incidence of acute radiation dermatitis in comparison to placebo using RTOG/EROTC criteria.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211029052907N2**
Registration date: **2022-02-14, 1400/11/25**
Registration timing: **prospective**

Last update: **2022-02-14, 1400/11/25**
Update count: **0**

Registration date
2022-02-14, 1400/11/25

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
2022-03-21, 1401/01/01

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

Evaluation of effectiveness and safety of montelukast gel in prevention of acute radiation dermatitis in breast cancer patients .

Public title

Evaluation of montelukast gel effect on prevention of radiation acute dermatitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Adult females (age ≥18 years) with a histologically confirmed diagnosis of localized invasive breast carcinoma Scheduled to receive adjuvant radiotherapy at least 50 Gy after breast surgery (breast-conserving surgery or mastectomy)

Exclusion criteria:

Prior history of radiotherapy to the treatment field Inflammatory or metastatic breast carcinoma Concurrent chemotherapy with RT (trastuzumab and hormonal therapy were allowed) Generalized skin disorders Connective tissue disorders Untreated surgical wounds Known allergy or hypersensitivity history to montelukast or any ingredients of the gel

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

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

Patients, researchers, and radiooncologists will not be aware of the patients' allocated gel.

Placebo

Used

Assignment

Single

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

2022-01-16, 1400/10/26

Ethics committee reference number

IR.ZUMS.REC.1400.450

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

The primary end point is to determine whether the montelukast gel can reduce the incidence of acute radiation dermatitis in comparison to placebo.

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

The secondary outcomes are to assess if montelukast gel reduces radiotherapy-induced symptoms such as pain and moist desquamation and improves the skin-related

quality of life as compared to placebo.

Timepoint

Patients will be evaluated for radiotherapy-induced symptoms such as pain and moist desquamation weekly after every fifth RT session. 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 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. The worst experienced pain will be evaluated using a visual analog scale. The skin-related quality of life of the patients was appraised using the Dermatology life quality index (DLQI) score.

Intervention groups

1

Description

Intervention group: montelukast gel

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

Web page address

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
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Position
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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

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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