

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the efficacy of topical Mometasone 0.1% and topical Hydrocortisone 1% and placebo in the prevention of acute radiation dermatitis in breast cancer patients

Protocol summary

Study aim

Comparison of the efficacy of topical Mometasone 0.1% and topical Hydrocortisone 1% and placebo in the prevention of acute radiation dermatitis in breast cancer patients

Design

The study is a three arm parallel group phase 3 prospective clinical randomized trial with placebo control and is triple blinded. Random allocation is simple and carried out with statistical software SPSS 22.

Settings and conduct

Sampling is simple and patients are selected from breast cancer patients who come for adjuvant radiation treatment to Omid hospital in Esfahan. One check list is filled for each patient about her information and disease and radiation treatment protocol. Persons who prescribe the treatment and assess and analysis the data as well as patients will be blind to the drug. All explanation about who to use drugs will be given to the patients verbally and with brochures. If radiation dermatitis occur, the grade is determined according to CTCEA(V4) scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with breast cancer who had surgery and should undergo breast radiation as adjuvant treatment; Exclusion criteria: Past history of skin disease like eczema and psoriasis, past history of connective tissue disease like lupus erythematosus and scleroderma, recurrent or metastatic breast cancer, past radiation to the skin of treatment field.

Intervention groups

Intervention group: Mometasone 0.1% cream;
Hydrocortisone 1% cream Control group: placebo which is base cream of interventional creams

Main outcome variables

radiation dermatitis grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180222038825N1**

Registration date: **2018-03-28, 1397/01/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-28, 1397/01/08**

Update count: **0**

Registration date

2018-03-28, 1397/01/08

Registrant information

Name

Mahsa Kianinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 8005

Email address

mahsa.kianinia@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of topical Mometasone 0.1% and topical Hydrocortisone 1% and placebo in the prevention of acute radiation dermatitis in breast cancer patients

Public title

The effect of topical Mometasone 0.1% and topical Hydrocortisone 1% in the prevention of acute radiation dermatitis of breast

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with breast cancer who had breast conservative surgery and should undergo breast radiation as adjuvant treatment

Exclusion criteria:

Past history of skin disease like eczema and psoriasis
Past history of connective tissue disease like lupus erythematosus and sclerodermia recurrent or metastatic breast cancer
Past radiation to the skin of treatment field

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization is simple and this will be done with statistical software SPSS 22.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Persons who prescribe the treatment and assess the results and also the patients are blind to the given drug; so someone else will put the drugs in the packets according to the random allocation list.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar-Jerib Ave

City

Esfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2017-02-22, 1395/12/04

Ethics committee reference number

IR.MUI.REC.1396.3.111

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Radiation dermatitis grade

Timepoint

weekly after initiation of radiotherapy until the end of whole breast radiation

Method of measurement

Common Terminology Criteria for Adverse Events v4.0 (CTCAE) scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Topical cream Mometasone 0.1%. The cream should be used once a day which is used after radiation. Also Patients will be instructed to wash skin with baby shampoo before radiation and no any cream should be on the skin. On Thursdays and Fridays that radiation will not be done, patients should use the cream on the skin once a day. This cream is manufactured by Behvazan pharmaceuticals company in Iran.

Category

Treatment - Drugs

2

Description

Intervention group 2: Topical cream Hydrocortisone 1%. The cream should be used once a day which is used after radiation. Also Patients will be instructed to wash skin with baby shampoo before radiation and no any cream should be on the skin. On Thursdays and Fridays that radiation will not be done, patients should use the cream on the skin once a day. This cream is manufactured by Emad Darman Pars pharmaceuticals company in Iran.

Category

Treatment - Drugs

3

Description

Control group: Base cream. The cream should be used once daily which is after radiation is done. Also Patients will be instructed to wash skin with baby shampoo before radiation and no cream should exist on the skin. On Thursdays and Fridays that radiation will not done, patients should use the cream once daily on the skin. This cream is manufactured in D.r Shahtalebi Lab in Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Mahsa Kianinia

Street address

Omid hospital, Motahari St, Khayam St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahsa Kianinia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Omid hospital, Khayam St, Motahari St

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available