Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of olive oil and calcium hydroxide emulsion on radiation radiation-induced dermatitis in breast cancer patients referred to Adjuvant RadiationTherapy

Protocol summary

Study aim

Determining the effect of olive oil and calcium hydroxide emulsion in reducing radiation dermatitis caused by radiotherapy in breast cancer patients who are candidates for adjuvant radiotherapy who were transferred to Parsian Shahrekord Center.

Design

Two-blind clinical trial on 120 female patients and randomly divided into four groups using the relevant software.

Settings and conduct

The patients are divided into four groups of 20 people by random assignment method. The medicine is placed in the breast, supraclavicular and axillary surgery site of the same side 30 minutes before the start of radiation therapy. All the products used in the study are completely identical in appearance and packaging, and their contents are indicated by labels in English letters.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 20 to 80 years who have undergone breast tumor surgery and are indicated for adjuvant radiotherapy. The pathology is breast invasive carcinoma. Patients who have a mass larger than 5 cm and at least one lymph node are involved and have a lumen. Pre-menopausal and post-menopausal age. Do not use any other topical medication during treatment. Exclusion criteria: diabetic patients and those with inflammatory breast carcinoma. People with known allergies to olive oil and calcium hydroxide. Those with scleroderma or disease They have lung parenchyma.

Intervention groups

First group: routine radiotherapy treatment + olive oil Second group: routine radiotherapy + olive oil along with calcium hydroxide The third group: routine radiotherapy treatment + castor oil Fourth group: routine treatment of radiotherapy + castor oil with calcium hydroxide

Main outcome variables

radiation-induced dermatitis (erythema, dry desquamative, wet desquamative, necrosis)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051571N1**
Registration date: **2023-06-07, 1402/03/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-07, 1402/03/17**
Update count: **0**

Registration date

2023-06-07, 1402/03/17

Registrant information

Name

Reyhaneh Habibiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-01, 1400/04/10

Expected recruitment end date

2023-10-02, 1402/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of olive oil and calcium hydroxide emulsion on radiation radiation-induced dermatitis in breast cancer patients referred to Adjuvant RadiationTherapy

Public title

Investigating the effect of emulsion containing olive oil and calcium in reducing radiation dermatitis caused by radiotherapy in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 20 to 80 years who have undergone breast tumor surgery and are indicated for adjuvant radiotherapy (both MRM and BCS) Its pathology type is invasive breastbe carcinoma Patients with a mass larger than 5 cm and at least one lymph node involved and lampooning Menopausal premenopause and postmenopausal age Do not use any other topical medication during treatment

Exclusion criteria:

Diabetic patients Those with inflammatory breast carcinoma. People with known allergies to olive oil and calcium hydroxide. People with scleroderma or lung parenchymal disease.

Age

From **20 years** old to **80 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

In order to better manage the implementation of the experiment and the number of samples in the groups, the random block method is used. For this purpose, the eligible conditions for entering the study were assigned to groups A, B, C, and D, respectively, by random and random block method in blocks of eight people. We considered the number of samples in each block to be twice the number of groups, considering that the sample volume was equal to 120 people, for this purpose, 15 envelopes were prepared and we named them in order from number 1 to 15. Each envelope had eight identical cards. . Two cards were randomly assigned to each group and group labels with letters A, B, C and D were inserted on them. At the time of entering the study, the envelopes were opened in order and a card from abroad, the letter named on the card, showed the specific group of the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since all the products used in the study are completely identical in terms of appearance and packaging and are inside non-transparent sprayers, and their contents are indicated by the label with English letters by the pharmacologist and using rose essence according to the pharmacologist's opinion. are the same, residents and patients do not have any information about the content inside the nebulizer.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Parastar Aven.Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2021-05-26, 1400/03/05

Ethics committee reference number

IR.SKUMS.REC.1400.058

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-induced dermatitis (erythema, dry

desquamative, wet desquamative, necrosis)

Timepoint

At the beginning of the study and then at the end of the first, second, third and fourth week.

Method of measurement

RTOG questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: routine radiotherapy treatment + castor oil, which is sprayed on the target area half an hour before radiotherapy, like other groups.

Category

Treatment - Drugs

2

Description

Intervention group: Routine treatment of radiotherapy + olive oil ointment 10 mm half an hour before the start of radiotherapy for 28 sessions

Category

Treatment - Drugs

3

Description

Intervention group: routine radiotherapy treatment + olive oil ointment with calcium hydroxide 10 mm half an hour before the start of radiotherapy for 28 sessions from Nik Darman company and with a percentage of 3%.

Category

Treatment - Drugs

4

Description

Intervention group: Routine radiotherapy treatment + castor oil ointment with calcium hydroxide 10 mm half an hour before the start of radiotherapy for 28 sessions from Nik Derman company and with a percentage of 3%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahrekord Parsian Hospital

Full name of responsible person
Rouh allah Maasoumi

Street address
Parastar Aven.Hajar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Mehraban Sadeghy

Street address
Parastar Aven

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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Reyhaneh Habibiyan

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work

Internal Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Undecided - It is not yet known if there will be 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
Title and more details about the data/document
Only part of the data such as information about the main outcome or the like can be shared.
When the data will become available and for how long
2021-2022
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
I have not decided yet
From where data/document is obtainable
I have not decided yet
What processes are involved for a request to access data/document
I have not decided yet
Comments