

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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

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

#### 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

#### 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 Habibiyani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3222 0016

###### Email address

st-habibiyani.r@skums.ac.ir

##### 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 breast carcinoma Patients with a mass larger than 5 cm and at least one lymph node involved and lamponing 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

###### **City**

Shahrekord

###### **Province**

Chahar-Mahal-va-Bakhtiari

###### **Postal code**

8816754633

###### **Phone**

+98 38 3222 0016

###### **Email**

St-habibiyan.r@skums.ac.ir

### **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

###### **City**

Shahrekord

###### **Province**

Chahar-Mahal-va-Bakhtiari

###### **Postal code**

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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 Habibiyani

##### **Position**

Resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Internal Medicine  
**Street address**  
Parastar Aven.Hajar Hospital  
**City**  
Shahrekord  
**Province**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Reyhaneh Habibiyar  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Reyhaneh Habibiyar  
**Position**  
Resident  
**Latest degree**

Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
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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