Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of sesame oil versus placebo in the management of acute radiation-induced dermatitis in breast cancer patients

Protocol summary

Study aim
Use of sesame oil in the treatment of acute dermatitis caused by radiotherapy in breast cancer patients

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 40 patients. For randomization after registration of eligible patients, they are assigned to treatment groups (sesame oil and placebo) based on a random algorithm following the dynamic allocation procedure.

Settings and conduct
The study to evaluate the effectiveness of sesame oil on the complication of acute dermatitis caused by radiotherapy in non-metastatic female patients aged 18 to 75 years with breast cancer undergoing treatment in Babol University of Medical Sciences and patients will be randomly divided into 2 groups. One group will be treated with paraffin (as placebo) and the other group will be treated with sesame oil, which are equalized in terms of color, shape, consistency and odor, and placebo and sesame oil in the same and impossible dishes. In this study, patients and researchers were blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Non-metastatic female patients aged 18 to 75 years with breast cancer who underwent lumpectomy; Completion of the chemistry cycle; Exclusion criteria: active infection; vascular collagen diseases; previous history of radiotherapy

Intervention groups
Candidates will be randomly assigned to two groups. These patients receive either sesame oil (experimental group) or Vaseline (placebo group)

Main outcome variables
Radiotherapy dermatitis based on the staging system of the Radiation Oncology Group (RTOG)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120707010205N9**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**
Update count: **0**

Registration date
2021-07-11, 1400/04/20

Registrant information

Name
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Name of organization / entity
Babol University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-03, 1400/04/12

Expected recruitment end date
2021-08-03, 1400/05/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of sesame oil versus placebo in the management of acute radiation-induced dermatitis in breast cancer

patients

Public title
The effectiveness of sesame oil in breast radiotherapy burns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients should complete the adjuvant chemotherapy before starting bilateral breast radiotherapy. Non-metastatic female patients with breast cancer who underwent lumpectomy Patients should be 18 to 75 years old
Exclusion criteria:
Patients with collagen-vascular diseases Patients with a history of previous radiotherapy Having an active infection during the study Patients with allergies to sesame oil (or placebo)
Age
From **18 years** old to **75 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this method, packages containing medicine or placebo are placed in the box as a mixture, and when offered to the candidates, without looking inside the box, one of the packages is randomly selected and given to the candidate. The package containing the placebo is marked with the letter A and the package containing the medicine is marked with the letter B.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, sesame and paraffin oils are completely identical in terms of color, shape, consistency and smell, and are placed in the same containers so that the contents of the containers are not visible in terms of shape, color and consistency for the researcher and the patient. Somehow it is planned that the participant and the researcher They do not know which of the two control or test groups Sesame or placebo oil is given.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences' Ethics Committee
Street address
Ganje-Afrouz St.
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4717641367
Approval date
2021-07-03, 1400/04/12
Ethics committee reference number
IR.MUBABOL.REC.1400.165

Health conditions studied

1

Description of health condition studied
acute radiation-induced dermatitis in breast cancer patients
ICD-10 code
L58.9
ICD-10 code description
Radiodermatitis, unspecified

Primary outcomes

1

Description
score of acute dermatitis according to the staging system of the Radiation Oncology Group (RTOG)
Timepoint
At the beginning of the study (before the intervention) and 7, 14 and 21 and the last day after the start of sesame oil consumption
Method of measurement
RTOG criteria to evaluate acute skin reaction

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sesame oil: After each session of radiotherapy, patients should use 3 cc of sesame oil in the breast area that has undergone radiotherapy so that the solution is spread evenly on the skin surface and apply sesame oil once after each radiotherapy Continue until the end of the radiotherapy course (30 sessions).

Category
Treatment - Drugs

2

Description
Control group: Placebo paraffin: After each radiotherapy session, patients should use 3 cc of placebo in the breast area undergoing radiotherapy so that the solution is evenly distributed on the skin surface and take placebo once until the end of the radiotherapy course. (30 sessions) Continue.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Babol 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

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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
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