Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluating the intensity of dermatitis caused by radiotherapy in breast cancer patients with or without using quercetin

Protocol summary

Study aim
Investigating the effect of quercetin on the severity of dermatitis caused by radiotherapy in patients with breast cancer

Design
Clinical trial with a control group, with parallel groups, Triple-blind, randomized, phase 3 on 92 patients. Sealedenvelop.com was used for randomization.

Settings and conduct
The study is conducted in Shahid Rajaei Hospital, Babolsar. Medicines are placed in tubes of the same shape and without the researcher and the patient knowing the contents of each tube, medicines are given to patients with the help of a nurse. Group 1 receives quercetin and the control group receives placebo. Patients are asked to apply the medicine twice a day after each radiotherapy session (once after radiotherapy and once at night).

Participants/Inclusion and exclusion criteria
Women with breast cancer in the age range of 30 to 70 years who underwent surgery and chemotherapy and after 3 to 4 weeks of chemotherapy, referred to Shahid Rajaei Hospital in Babolsar, Mazandaran province to receive adjuvant radiotherapy, were included in the study. Patients who have an underlying disease and a history of inflammatory skin disease, or are in stage 4 ,have undergone radiotherapy for palliation or have a history of severe drug sensitivity are excluded from the study.

Intervention groups
Medicines are placed in tubes of the same shape. Group 1 receives quercetin and the control group receives placebo. Patients are asked to apply the medicine twice a day after each radiotherapy session (once after radiotherapy and once at night).

Main outcome variables
The severity of dermatitis caused by radiotherapy based on the RTOG classification, the time of onset or change in the intensity of symptoms and the intensity of pain in patients based on the Visual Analogue Scale index.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230509058138N1**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date
2023-12-18, 1402/09/27

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the intensity of dermatitis caused by radiotherapy in breast cancer patients with or without using quercetin

Public title
The effect of quercetin on dermatitis caused by radiotherapy in breast cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
women with breast cancer who are between 30 to 70 years old they underwent breast lumpectomy surgery after 3-4 weeks of surgury, they came for radiotherapy

Exclusion criteria:
patients who have an underlying disease and a history of skin inflammation patients who are in stage 4 or are undergoing radiotherapy for palliation patients with Modified Radical Mastectomy must not be included in the study. Patients with a history of severe allergy

Age
From **30 years** old to **70 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
During this double-blind randomized clinical trial, patients are divided into two random groups using blocks 4 and 10. Medicines are placed in tubes of the same shape and without the researcher and the patient knowing the contents of each tube, the medicines are given to the patients with the help of a nurse.

Blinding (investigator's opinion)
Triple blinded

Blinding description
During this double-blind clinical trial, the participants (patients), the researcher, the outcome assessor and the data analyst have been kept blind. Ointments containing Quercetin and placebo are placed in tubes of the same shape, by a colleague not involved in the implementation process of the project, and without the researcher and the patient knowing the contents of each tube, the medicines are given to the patients with the help of a nurse.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Health Research Institute - Babol University of Medical Sciences

Street address
Gangafrouz Ave., Abolhasani Blvd., Babol Town

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Approval date
2023-12-10, 1402/09/19

Ethics committee reference number
IR.MUBABOL.HRI.REC.1402.134

Health conditions studied

1

Description of health condition studied
Dermatitis

ICD-10 code
L58.0

ICD-10 code description
Acute radiodermatitis

Primary outcomes

1

Description
Severity of radiotherapy-induced dermatitis according to RTOG classification

Timepoint
The severity of radiation dermatitis is evaluated once a week from the time of entering the study until the completion of the radiotherapy treatment.

Method of measurement
Based on the criteria of Radiation Therapy Oncology Group

Secondary outcomes

1

Description
The time which symptoms of dermatitis develop

Timepoint
Once a week from the beginning of the study to the end

of the radiotherapy duration

Method of measurement

We record the time when the symptoms of dermatitis developed in the weekly examination according to the opinion of the specialist who evaluates the patients.

2

Description

Severity of patients' pain

Timepoint

Once a week from the beginning of the study to the end of the radiotherapy duration

Method of measurement

We record the change in pain intensity in the weekly examination according to the opinion of the specialist who evaluates the patients. The pain intensity of the patients is measured using the Visual Analogue Scale index.

Intervention groups

1

Description

Intervention group: Women with breast cancer in the age range of 30 to 70 years who underwent surgery (lumpectomy) and chemotherapy and after 3 to 4 weeks of chemotherapy, referred to receive adjuvant radiotherapy, are included in the study. The combination of quercetin from Sigma company is given to patients at a dose of 0.2%. After each radiotherapy session, patients are asked to apply the drug twice a day (once after radiotherapy and once at night) for 6 weeks using rubbing method. Also, before each radiotherapy session, patients should use Dove soap to wash the treatment area so that no trace of the drug remains.

Category

Treatment - Drugs

2

Description

Control group: The placebo contains carboxymethyl cellulose with food coloring that is similar in color to the quercetin compound. After each radiotherapy session, patients are asked to apply the drug twice a day (once after radiotherapy and once at night) for 6 weeks using rubbing method. Also, before each radiotherapy session, patients should use Dove soap to wash the treatment area so that no trace of the drug remains.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Contact

Name of organization / entity

Babol University of Medical Sciences

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student
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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