Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness and safety of 5% gel of extract of Nigella sativa L. to prevent radio-dermatitis in breast cancer patients

Protocol summary

Study aim

The aim of the study is to evaluate the efficacy and safety of Nigella sativa L. extract gel in the prevention of acute radiodermatitis in the breast cancer patients.

Design

This study is a 2-arm, double-blinded, randomized clinical trial, designed to evaluate the efficacy and safety of Nigella sativa L. extract gel and placebo in breast cancer patients undergoing radiotherapy to the breast (breast conservation surgery) or chest wall (postmastectomy).

Settings and conduct

Eligible patients receiving radiation therapy will be recruited from Imam Khomeini Hospitals affiliated to Mazums. The patients will be received either 45 Gy in 20 fractions or 50 Gy in 25 fractions. The skin type of patients will be determined with Fitzpatrick skin type scale before the use of topical products and skin care procedures will be taught on the basis of the MASCC Skin Toxicity Study Group's Guide. The use of topical products is twice daily in radiotherapy period. Patients, clinical caregiver, outcome evaluator, and researcher have no information about the patients ' treatment group.

Participants/Inclusion and exclusion criteria

The women aged more than 18 years with a confirmed histological diagnosis of ductal or lobular breast carcinoma, who received adjuvant radiotherapy after breast surgery, will be included in this study.

Intervention groups

Patients will be randomly assigned into two groups of gel 5% of Nigella sativa L. extracts and placebo gel.

Main outcome variables

Dermatologic reactions and pain were evaluated weekly during the radiotherapy period, and the results were based on Radiation Therapy Oncology Group and National Cancer Institute criteria: Common Terminology Criteria for Adverse Events v5.0 for skin reactions and numerical scaling scale for pain will be recorded. Also, the patients' quality of life will be evaluated based on the Dermatology Life Quality Index Questionnaire biweekly.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090813002342N7**
Registration date: **2018-08-08, 1397/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-08, 1397/05/17**
Update count: **0**

Registration date

2018-08-08, 1397/05/17

Registrant information

Name

Mohammad Reza Rafati

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness and safety of 5% gel of extract of Nigella sativa L. to prevent radio-dermatitis in breast cancer patients

Public title
Effectiveness of Black cumin gel in radio-dermatitis in breast cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed histological diagnosis of ductal or lobular breast Carcinoma Adjuvant radiotherapy after surgery
Exclusion criteria:
Patients with previous radiotherapy to the chest or breast Patients with concomitant adjuvant or neoadjuvant chemotherapy Generalized skin or connective tissue disorders Unhealed surgical wounds A known allergy to Black cumin or any excipient of gel formulation

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be treated with 5% Nigella sativa gel and placebo gel using the blocking method. The generation of random numbers is done with Random allocation software, and 60 samples will be assigned in 6 blocks of 10. All products used in the study are completely identical in terms of appearance and packaging, and their content will be characterized by a four-digit code.

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 their content is characterized by a four-digit code, patients do not have any information about their treatment group. Also, the patient's treatment group is determined randomly, according to the previously defined coding. Only the secretary of radiotherapy ward who offers the product to the patients knows the treatment groups of the patients. Clinical caregiver (physician), researcher and evaluator of the outcome (researcher) have no information on the treatment group of patients.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Vice-Chancellor for Research of Mazandaran University of Medical Sciences, Moallem Square
City
Sari
Province
Mazandaran
Postal code
4817844718

Approval date
2018-07-11, 1397/04/20

Ethics committee reference number
IR.MAZUMS.REC.1397.1731

Health conditions studied

1

Description of health condition studied
radiodermatitis

ICD-10 code
L58

ICD-10 code description
Radiodermatitis

Primary outcomes

1

Description
The time of incidence of radio-dermatitis

Timepoint
At the beginning of the study (before the intervention) and weekly until the end of the radiotherapy period

Method of measurement
Radiation therapy oncology group (RTOG) و National Cancer institute: Common Terminology Criteria for Adverse Events v5.0 (CTCAE) Scales

Secondary outcomes

1

Description
The quality of life of patients

Timepoint

Biweekly after initiation of radiotherapy period

Method of measurement

Dermatology Life Quality Index (DLQI) questionnaire

Intervention groups

1

Description

Intervention group: 5% gel of black seed extract

Category

Treatment - Drugs

2

Description

Control group: Placebo gel

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy ward of Imam khomeini hospital

Full name of responsible person

Dr. Saeed Davodian

Street address

Razi Street

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Mazandaran

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4816633131

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+98 11 3337 7168

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

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Vice Chancellor for Research, Moallem square

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Raza Rafati

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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