Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effectivness of hydrogel containing Purslane extract in prevention and reduction of severity of radiotherapy-induced acute dermatitis in breast cancer patients

Protocol summary

Study aim

Ḍtermination of the effectivness of hydrogel containing Portulaca oleracea extract on the management of radiotherapy-induced mucositis

Design

A double-blind, randomized, placebo-controlled, Phase 2-3 clinical trial study will be performed on 80 individuals divided into two groups.

Settings and conduct

The study will be performed in patients referred to the clinics of Babol and Mashhad University of Medical Sciences. Patients are randomly assigned medication and placebo after obtaining informed consent. Patients will use the hydrogel twice a day based on the fingertip unit for six weeks and will be evaluated weekly by an oncologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients with diagnosed breast cancer, age 18 years and older, no skin tumour tissue, no concomitant chemotherapy, no previous chest radiotherapy, minimum 50 Gy radiation during treatment, BMI 20-30, Breast-conserving surgery
Exclusion criteria: patients with underlying diseases, hypersensitivity to Portulaca oleracea, patients with metastatic carcinoma to the breast, Inability of the patient to implement the treatment protocol

Intervention groups

Placebo group: Placebo hydrogel containing glycerin and green dye made by Mashhad University of Medical Sciences, Intervention group: hydrogel containing 2% Portulaca oleracea extract and glycerin content made by Mashhad University of Medical Sciences

Main outcome variables

Incidence and severity of chemotherapy-induced mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038199N8**
Registration date: **2021-07-27, 1400/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-27, 1400/05/05**
Update count: **0**

Registration date

2021-07-27, 1400/05/05

Registrant information

Name

Vahid Reza Askari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2264

Email address

askariv941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effectivness of hydrogel containing Purslane extract in prevention and reduction of severity of radiotherapy-induced acute dermatitis in breast cancer patients

Public title
The effect of Portulaca oleracea hydrogel on the prevention of radiotherapy-induced dermatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female patients diagnosed with breast tissue cancer Age over 18 years No concomitant chemotherapy No previous radiotherapy to the chest area Minimum radiation of 50 Gy during treatment BMI 20-30 Breast conserving surgery

Exclusion criteria:
Existence of underlying diseases hypersensitivity to Portulaca oleracea Patients with metastatic carcinoma to the breast Inability of the patient to implement the treatment protocol

Age
From **18 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by block method, the size of blocks is equal to four with two members A and B in a ratio of 1: 1. Based on the sample size, 20 blocks are numbered in a different order from 1 to 20 and a random sequence of 20 blocks is determined using the site "www.Randomaize.com", then the sequence of treatment groups A and B is determined in envelopes with number 1 Up to 80, with the inclusion of each eligible person, the envelope corresponding to the person's number is opened and the treatment group is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the use of a placebo similar to the intervention treatment, the physician associated with the participants and participants will not be informed of the assigned treatment. Also, the analyst will be unaware of the treatment assigned to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals codes A and B. The placebo will be very similar in treatment in terms of shape, consistency, packaging, and smell.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2021-06-19, 1400/03/29

Ethics committee reference number
IR.MUMS.REC.1400.070

Health conditions studied

1

Description of health condition studied
Radiotherapy-induced mucositis is breast-conserving cancer patients

ICD-10 code
L58.0, L27

ICD-10 code description
Acute radiodermatitis, Localized skin eruption due to drugs and medicament

Primary outcomes

1

Description
Incidence of dermatitis

Timepoint
At the beginning of the study and every week for 6 weeks

Method of measurement
Physician evaluation checklist of incidence and severity of disease for the radiotherapy oncology group (RTOG)

2

Description

Severity of dermatitis

Timepoint

At the beginning of the study and every week for 6 weeks

Method of measurement

Physician evaluation checklist of incidence and severity of disease for the radiotherapy oncology group (RTOG)

Secondary outcomes

1

Description

Quality of life

Timepoint

at the beginning and the end of the study

Method of measurement

Ware & Sherbourne's quality of life questionnaire

Intervention groups

1

Description

Control group: Patients undergo radiotherapy, will receive placebo hydrogel containing glycerin and green dye made by Mashhad University of Medical Sciences. Patients will use this hydrogel twice a day (at least two hours before radiotherapy and at least two hours after radiotherapy) and topically for 6 weeks.

Category

Placebo

2

Description

Intervention group: Patients undergo radiotherapy, will receive hydrogel containing 2% Portulaca oleracea extract and glycerin content made by Mashhad University of Medical Sciences. Patients will use this hydrogel twice a day (at least two hours before radiotherapy and at least two hours after radiotherapy) and topically for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Dr Vahid Reza Askari

Street address

Mashhad University of Medical Science, Azadi Square

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2

Recruitment center

Name of recruitment center

Clinics affiliated to Babol University of Medical Sciences

Full name of responsible person

Dr Danial Fazilatpanah

Street address

Babol University of Medical Science, Ganj Afrouz Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

Assistant professor of clinical pharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of medicine, Paradise of University, Vakil-Abad Blvd., Azadi Sq., Mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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