

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Preparation and evaluation of the effect of hydrogel containing Saffron petal extract in prevention and reduction of severity of radiotherapy-induced acute dermatitis in breast cancer patients

Protocol summary

Study aim

Preparation and determination of the effect of hydrogel containing Saffron petal 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. Randomization will be done using the blocking method and random selection with the help of the Randomize.com randomization site.

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-red mixed dye made by Mashhad University of Medical Sciences, Intervention group: hydrogel containing 8% Saffron petal 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: **IRCT20180103038199N7**

Registration date: **2021-07-07, 1400/04/16**

Registration timing: **prospective**

Last update: **2021-07-07, 1400/04/16**

Update count: **0**

Registration date

2021-07-07, 1400/04/16

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

2021-08-23, 1400/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and evaluation of the effect of hydrogel containing Saffron petal extract in prevention and reduction of severity of radiotherapy-induced acute dermatitis in breast cancer patients

Public title

The effect of Saffron petal 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 Saffron petal
Patients with metastatic carcinoma to the breast
Inability of the patient to implement the treatment protocol

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization takes place in three stages: 1- Creating a random sequence: in this stage of block randomization: quadruple blocks; Possible scenarios for two groups of the experiment: Six quadruple modes including: 1- AABB, 2- ABAB, 3-BBAA, 4-BABA, 5-BAAB and 6- ABBA Possible scenarios for two groups of 40 equal to $10 = 80/4$ Randomly write 20 blocks (using a table of random numbers) Write the final equivalent block Coding and allocating patients to receive medicine or placebo after opening the envelopes from number 1 to number 80, respectively. 2- Hide random allocation, which is done in the form of coded boxes with the random sequence with the help of random numbers table. In this method, a number of boxes of the same shape and size are numbered in random order and contain a medicine or placebo that have exactly the same regarding the appearance. 3- Execution of random allocation process: - The person who creates the random sequence: statistics consultant - The person who evaluates and registers the participants in terms of inclusion and exclusion criteria: Student of the project - The person who assigns the participants to the groups: Oncologist

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 Hoveyze 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 and 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: Placebo hydrogel containing glycerin and green-red mixed dye made by Mashhad University of Medical Sciences

Category

Placebo

2

Description

Intervention group: hydrogel containing 8% Saffron petal extract and glycerin content made by Mashhad University of Medical Sciences

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2000

Email

askariv@mums.ac.ir

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 Square

City

Babol

Province

Razavi Khorasan

Postal code

Phone

+98 11 3219 9592

Email

drfazilatpanah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2264

Fax**Email**

askariv@mums.ac.ir

Person responsible for scientific 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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2264

Fax**Email**

askariv@mums.ac.ir

Person responsible for updating data

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2264

Fax**Email**

askariv@mums.ac.ir

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