

# 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 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 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

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+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

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###### **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

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## 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

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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**

Assistant professor of clinical pharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Fax**

## 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