# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 Randomaize.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)

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**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

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Razavi Khorasan

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**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

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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**

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## Sponsors / Funding sources

### 1

**Sponsor**

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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

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## Person responsible for updating data

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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