

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of Plantago major leaf gel compared to placebo on prevention of acute radiation dermatitis in breast cancer patients: A double blind, randomized clinical trial

#### Protocol summary

##### Study aim

determining the effect of Plantago major leaf gel compared to placebo on prevention of acute radiation dermatitis in breast cancer patients

##### Design

Randomized clinical trial with control group ,double blind, phase 2, on 80 patients. Random allocation software 2.0 uses for randomization.

##### Settings and conduct

The study site is Shiraz Namazi hospital which is the center for cancer patients radiotherapy. The study is double blind. The patients and researchers are blinded.The duration of treatment is 7 weeks. Patients Will be followed up for the duration of radiation and 2 weeks after the last radiation therapy session and visited weekly.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: breast cancer patients who need external radiotherapy 18 years old and more exclusion criteria: previous chest radiotherapy skin tumor rash,ulcer,scar connective tissue disease diabetes mellitus concomitant chemotherapy

##### Intervention groups

Eighty patients are selected from the target population and randomly divided into two equal groups. Patients will be use plantago major gel in intervention group and placebo in control group. Patients in both groups will be instructed to cover the area under radiation with a thin layer of topical gel twice a day (morning and night). Treatment in both groups will continue from the first day of radiation therapy to two weeks after the last radiation therapy session.

##### Main outcome variables

Dermatitis grade

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150830023823N4**

Registration date: **2021-07-31, 1400/05/09**

Registration timing: **prospective**

Last update: **2021-07-31, 1400/05/09**

Update count: **0**

##### Registration date

2021-07-31, 1400/05/09

##### Registrant information

##### Name

Ali Tavakoli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3233 1028

##### Email address

tavakkolia@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-21, 1400/05/30

##### Expected recruitment end date

2022-05-20, 1401/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of Plantago major leaf gel compared to placebo on prevention of acute radiation dermatitis in breast cancer patients: A double blind, randomized clinical trial

**Public title**

Effect of Plantago major leaf gel on prevention of acute radiation dermatitis in breast cancer patients

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with definitive diagnosis of breast cancer who have undergone quadrantectomy treatment. indication of external radiotherapy 18 years old and more

**Exclusion criteria:**

previous breast radiotherapy skin tumor rash, ulcer, scar connective tissue disorder diabetes melitus concomitant use of chemotherapy

**Age**

From **18 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: we use permutation block randomization method with block size of 4. Selected samples based on these blocks are placed in treatment intervention (A) and placebo intervention (B) groups. All possible blocks are arranged as follows: block1:AABB, block 2:ABAB, block 3:ABBA, block 4:BBAA, block 5:BABA, block 6:BAAB. Therefore, according to the sample size (80 subjects) we need 20 blocks. For generation a list of 80 random sequences by permutation block method, we use Random allocation software 2.0. We randomly select these blocks from 1 to 6. Using Random allocation software 2.0, we choose a random number between the numbers 1 to 6. For example, if number 6 is selected as the first block and number 2 as the second block, BAABABAB will be the random sequences according to which people enter the study. We continue this to generate a list of 80 random sequences. Finally, based on this random list, 40 patients will be allocated to group A and 40 patients to group B.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The placebo will be made in color, odor, package and other characteristics similar to plantago major gel so that the patients and the researchers can't distinguish between them.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz Medical School

**Street address**

Zand St.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134845794

**Approval date**

2021-04-05, 1400/01/16

**Ethics committee reference number**

IR.SUMS.MED.REC.1400.015

**Health conditions studied****1****Description of health condition studied**

Acute radio dermatitis

**ICD-10 code**

L58.0

**ICD-10 code description**

Acute radio dermatitis

**Primary outcomes****1****Description**

dermatitis grade

**Timepoint**

weekly for 7 weeks

**Method of measurement**

observation by physician with Common Terminology Criteria for Adverse Events(CTCAE) version 4

**Secondary outcomes****1****Description**

burning sensation grade

**Timepoint**

weekly

**Method of measurement**

Ask the patient with patient symptom scale

## 2

### **Description**

Pain

### **Timepoint**

weekly

### **Method of measurement**

Ask the patient with patient symptom scale

## 3

### **Description**

pruritus

### **Timepoint**

weekly

### **Method of measurement**

Ask the patient with patient symptom scale

## **Intervention groups**

### 1

#### **Description**

Intervention group: The drug of the intervention group is Plantago major leaf gel. This topical skin gel is made by a pharmacist under the supervision of Shiraz School of Pharmacy. To prepare the topical form of the drug (gel), the Plantago major leaf extract will be added to the gel stand. The gel will also be subjected to microbial control and chemical evaluation. Patients will be instructed to cover the skin of the area under radiation with a thin layer of topical gel twice a day (morning and night). The duration of use is 7 weeks that will continue from the first day of radiation therapy till 2 weeks after the last radiation therapy session. To reduce the effect of bolus, it is recommended that the minimum interval between the use of the gel and the start of each the radiation therapy session be two hours. Patients are also urged to avoid using other topical compounds during treatment.

#### **Category**

Prevention

### 2

#### **Description**

Control group: placebo that will be applied by control group is the same gel stand used to preparing the plantago major gel. Placebo is also made by a pharmacist under the supervision of Shiraz School of Pharmacy. patients in this group will also be instructed to cover the skin of the area under radiation with a thin layer of topical gel (placebo) twice a day (morning and night). The duration of use is 7 weeks that will continue from the first day of radiation therapy till 2 weeks after the last radiation therapy session. It is also recommended for patients in this group that the minimum interval between the use of the gel and the start of each the radiation therapy session be two hours. Patients are also urged to avoid using other topical compounds during treatment.

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

radiotherapy department in Nemazi Hospital, Shiraz

##### **Full name of responsible person**

Zahra Salehi

##### **Street address**

Zand St, Medical School, Seventh floor, Persian  
Medicine Department

##### **City**

Shiraz

##### **Province**

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##### **Postal code**

7134845794

##### **Phone**

+98 71 3234 5145

##### **Email**

zsalehipediatric@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Abbas Rezaianzadeh

##### **Street address**

Zand St.

##### **City**

Shiraz

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##### **Postal code**

71348-14336

##### **Phone**

+98 71 3235 7282

##### **Fax**

+98 71 3212 2430

##### **Email**

vcrdep@sums.ac.ir

##### **Web page address**

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ali Tavakoli

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

for privacy

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available