

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

Fars

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

Province

Fars

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

Street address

Zand St, Medical School, Seventh floor, Persian

Medicine Department

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Email

tavakkolia@sums.ac.ir

Person responsible for scientific 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

Street address

Zand St, Medical School, Seventh floor, Persian

Medicine Department

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Email

tavakkolia@sums.ac.ir

Person responsible for updating data**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

Street address

Zand St, Medical School, Seventh floor, Persian

Medicine Department

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Email

tavakkolia@sums.ac.ir

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