Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
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Person responsible for updating data

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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