

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of prophylactic effect of aloe vera gel on radiation induced dermatitis in breast cancer patients.

Protocol summary

Summary

Purpose: Given the wide prevalence of breast cancer in females and radiation- induced dermatitis, a randomized trial designed to evaluate prophylactic effect of aloe vera gel on radiation induced dermatitis. Design: this is a randomized phase 2 clinical trial. Setting and conduct: Targeted population include 100 patients that receive radiotherapy in Namazee hospital. Patients randomly assign to intervention group or control group. Both groups receive radiotherapy. Then intervention group receive topical aloe vera gel on radiation therapy field twice a day and control group receive no treatment. The patients have been examined weekly and dermatitis grade is compared in both groups finally. Inclusion criterias include breast cancer patients with partial mastectomy, all ages, Female, No previous radiotherapy to breast area. Exclusion criterias include Having poor follow up and Using other local drugs concurrently. Intervention: all patients receive standard radiotherapy and Aloe vera gel was applied in intervention group. The main outcome variables: The endpoints of this study include grading of dermatitis and treatment interruption.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082129451N1**

Registration date: **2016-10-02, 1395/07/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-02, 1395/07/11

Registrant information

Name

Behnam Kadkhodaei

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

anamis compony

Expected recruitment start date

2015-11-30, 1394/09/09

Expected recruitment end date

2016-02-28, 1394/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylactic effect of aloe vera gel on radiation induced dermatitis in breast cancer patients.

Public title

Evaluation of prophylactic effect of aloe vera gel on radiation induced dermatitis in breast cancer patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: New diagnosed breast cancer patients with partial mastectomy who need to receive radiation therapy; All ages; Female; No previous radiotherapy to breast area; No systemic and dermatologic disease; The median time interval between end of chemotherapy and the beginning of irradiation ranged between 3 and 4

weeks. Exclusion criteria: Having poor follow up; Stopping radiotherapy by patient herself; The patient refuse to using aloe Vera gel; Using other local drugs concurrently.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz medical school ' Ethics Committee

Street address

Zand AVE, Namazee SQ, Shiraz medical school

City

Shiraz

Postal code

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.SUMS.MED.REC.1395.15

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

Primary outcomes

1

Description

Grading of dermatitis

Timepoint

weekly

Method of measurement

Rtog scoring for radiation induced dermatitis

Secondary outcomes

1

Description

Treatment interruption

Timepoint

weekly

Method of measurement

Review of the patient's medical file

Intervention groups

1

Description

Intervention group: all breast cancer patients with partial mastectomy that assigned to this group randomly and all of them receive standard radiotherapy. radiation doses was 50 Gy in 25 fractions by linac machine (6mv photon) and Aloe vera gel was applied twice a day with a thickness of 1-2 mm on the radiation therapy field from first day. 6-hour time period is recommended between two application of aloe vera gel.

Category

Treatment - Drugs

2

Description

Control group: All breast cancer patients with partial mastectomy that assigned to this group randomly, should receive radiotherapy. Radiation doses was 50 Gy in 25 fractions by linac machine (6mv photon).The patients did not receive any medication .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazee Teaching Hospital

Full name of responsible person

Dr.Behnam kadhodaie

Street address

Zand AVE, Namazee SQ

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr.Ali Poost Foroush Fard

Street address

Zand AVE, Central building

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty