Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 beast 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

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Name of organization / entity
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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 kadkhodaei

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
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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

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Person responsible for updating data

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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