

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

A comparison between the effects of aloe vera ointment versus placebo in prevention and treatment of acute proctitis induced by radiotherapy: a randomized controlled clinical trial

Protocol summary

Summary

This study is a prospective phase 2, double-blinded randomized, placebo controlled, single center clinical trial conducted at Radiotherapy Center of Imam Khomeini Hospital in Sari, Mazandaran province, Iran. If the patients aged older than 18 years and received pelvic radiation, they'd enter in the study. The patients will be randomized into two groups based on the table of random numbers, including 30 in each group. In this study, the effectiveness of aloe vera in prevention and treatment of acute radiation-proctitis is evaluated. The eligible patients are randomized as follow: topical ointment of aloe vera 3% BID or placebo ointment. If the patients troubled with acute proctitis symptoms during study, they will enter the second phase of study; they are randomized into one of the following groups: aloe vera ointment BID plus tablet sulfasalazine 500mg QID or placebo ointment BID plus tablet sulfasalazine 500mg QID. The patients are followed up weekly for 6 weeks and if they experience proctitis, therapy with aloe vera will be continued for 4 weeks more. The primary end points are proctitis development based on clinical presentation, the severity of proctitis based on Radiation therapy oncology group (RTOG) criteria and the second outcomes will be quality of life, quantitative CRP and social-psychological state based on Hospital Anxiety-Depression (HAD) scale .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606042027N6**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-05-30, 1395/03/10

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effects of aloe vera ointment versus placebo in prevention and treatment of acute proctitis induced by radiotherapy: a randomized controlled clinical trial

Public title

The effects of aloe vera ointment in proctitis induced by

radiotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: patients aged older than 18 years; patients with a history of pelvic radiation. Exclusion Criteria: Evidence of active infection; evidence of other sources of hematochezia including colon cancer, inflammatory bowel disease, and hemorrhoids; anal incontinence; anorectal fistula; anorectal stenosis; previous rectal surgery; pregnancy or breast feeding; female of child-bearing age not taking adequate contraception; known allergy to any ingredients of the ointments; concomitant use of antibiotics or steroids.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar square

City

Sari

Postal code

861-48175

Approval date

2016-05-11, 1395/02/22

Ethics committee reference number

IR.MAZUMS.REC.94-1196

Health conditions studied

1

Description of health condition studied

Acute Radiation Proctitis

ICD-10 code

62.7

ICD-10 code description

Radiation proctitis

Primary outcomes

1

Description

Development of proctitis

Timepoint

before intervention, then weekly for six weeks after intervention

Method of measurement

based on clinical presentation

2

Description

proctitis severity

Timepoint

before intervention, then weekly for six weeks after intervention

Method of measurement

based on Radiation Therapy Oncology Group (RTOG) criteria

Secondary outcomes

1

Description

Quality of life

Timepoint

before intervention, then weekly for six weeks after intervention

Method of measurement

based on questionnaire

2

Description

Quantitative CRP

Timepoint

before intervention, then weekly for six weeks after intervention

Method of measurement

based on patient's blood sample

3

Description

Social-Psychological state

Timepoint

before intervention, then weekly for six weeks after

intervention

Method of measurement

based on Hospital Anxiety-Depression (HAD) scale

Intervention groups

1

Description

Intervention group: aloe vera ointment 1 g twice daily from the first day of study for six weeks

Category

Treatment - Drugs

2

Description

Control group: placebo ointment 1 g twice daily from the first day of study for six weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Center of Imam Khomeini Hospital

Full name of responsible person

Adeleh Sahebnaasagh

Street address

Radiotherapy Center of Imam Khomeini Hospital, Sari, Mazandaran Province, Iran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Vice chancellor for research of Mazandaran University of Medical Sciences, Moallem Square, Sari

City

Sari

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Mazandaran 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

Faculty of Pharmacy, Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Position

Faculty member, Professor of Clinical Pharmacy

Other areas of specialty/work

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Web page address

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