

# 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

###### Name

Ebrahim Salehifar

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1311 6546

###### Email address

esalehifar@mazums.ac.ir

##### 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**

**Street address**

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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*