

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of the Effects of Aloe Vera and Placebo Ointment in the Prevention of Radiation-Induced Acute Proctitis in Prostate Cancer Patients

Protocol summary

Study aim

Determination of efficacy of Aloe vera ointment in the prevention of radiation-induced acute proctitis in patients with prostate cancer

Design

Randomized parallel groups randomizes double blind clinical trial. The sample size will be 56 cases (28 in each group).

Settings and conduct

This clinical trial will be conducted on patients over 18 years of age with prostate cancer at Babolsar Shahid Rajaei Hospital. Patients will be randomized to receive Aloe vera or placebo and the effect of Aloe vera ointment 3 % will be compared with placebo. Physician and patients will be blind regarding the grouping of the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Signing of informed consent form; Age over 18 years old; Patients with prostate cancer undergoing 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; known allergy to any ingredients of the ointments; concomitant use of antibiotics or steroids.

Intervention groups

Intervention groups included aloe vera ointment group and control group receiving aloe vera placebo.

Main outcome variables

Development of proctitis based on clinical presentation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090613002027N17**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of the Effects of Aloe Vera and Placebo Ointment in the Prevention of Radiation-Induced

Acute Proctitis in Prostate Cancer Patients

Public title

Evaluation of the effects of Aloe Vera Ointment in the radiation induced Proctitis in prostate cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being over 18 years old Prostate cancer patients whom are under pelvic Radiotherapy

Exclusion criteria:

Evidence of active infection Evidence suggesting other causes of bloody diarrhea, such as colon cancer, inflammatory bowel disease and hemorrhoids Fecal Incontinence Anorectal fistula Anal Stenosis History of surgery in the rectum area Any known Sensitivity of the components used in the ointment Concomitant use of antibiotics, Glucocorticoids and Sulfonamide compounds

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized according to block randomization with 4 cases in each block. For concealment, a 5 digits unique code will be obtained from Excel.

Blinding (investigator's opinion)

Double blinded

Blinding description

Aloe vera and placebo will be filled in identical containers, and the senior researcher will insert the unique code of each participant on the containers. The researcher and patient will not be aware of the type of intervention received.

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

Mazandaran University of Medical Sciences, kilometer 18 of Farah Abad road, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

861-48175

Approval date

2019-01-02, 1397/10/12

Ethics committee reference number

IR.MAZUMS.REC.1397.241

Health conditions studied

1

Description of health condition studied

Radiation-induced acute proctitis in prostate cancer patients

ICD-10 code

K62.7

ICD-10 code description

Radiation proctitis

Primary outcomes

1

Description

Development of Proctitis

Timepoint

Before intervention, then every 2 weeks for eight weeks after intervention

Method of measurement

Based on clinical presentation

2

Description

Proctitis severity

Timepoint

Before intervention, then every 2weeks for eight weeks after intervention

Method of measurement

Based on Radiation therapy oncology group (RTOG) and CTCAE-v5-2017 criteria

Secondary outcomes

1

Description

Social-Psychological state

Timepoint

Before intervention, then every 2weeks for eight weeks after intervention

Method of measurement

Based on Hospital Anxiety-Depression (HAD) scale

2

Description

Quality of life

Timepoint

Before intervention, then every 2weeks for eight weeks after intervention

Method of measurement

Based on questionnaire defines the Quality of Life from 0 to 5.

Intervention groups

1

Description

Intervention group: Aloe Vera ointment 3% for the first day of radiotherapy every 12 hours, rectal use for 2 months

Category

Prevention

2

Description

Control group: Placebo of Aloe Vera ointment 3% for the first day of radiotherapy every 12 hours, rectal use for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Radiation Therapy Center in Babolsar

Full name of responsible person

Abed Besmel

Street address

Shahid Rajaee Radiotherapy center, Shilat Square, Shariati Ave

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rajaee@mubabol.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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

Confidentiality of patients data

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