

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the efficacy of sucralfate ointment versus placebo in prevention of acute proctitis induced by radiotherapy in cancer patients: a randomized controlled clinical trial

Protocol summary

Summary

This study is a phase 2, double-blinded, randomized, placebo controlled, single center clinical trial conducted at Radiotherapy Center of Imam Khomeini Hospital in Sari. Patients aged over 18 years who receive pelvic radiation will be randomized into two groups including 30 participants in each group using random number table. In this study, the efficacy of sucralfate in prevention of acute radiation proctitis will be evaluated. The intervention group will receive topical sucralfate ointment and the control group will receive placebo ointment twice a day for six weeks. The patients will be followed in terms of occurrence of proctitis for 6 weeks. 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 secondary outcomes will be the effects of proctitis on lifestyle (by a method described by Kennedy et al., 2001), quantitative CRP and social-psychological state based on Hospital Anxiety-Depression (HAD) scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606042027N7**
Registration date: **2016-09-22, 1395/07/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-22, 1395/07/01

Registrant information

Name

Ebrahim Salehifar

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2015-11-21, 1394/08/30

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of sucralfate ointment versus placebo in prevention of acute proctitis induced by radiotherapy in cancer patients: a randomized controlled clinical trial

Public title

The efficacy of sucralfate in prevention of acute proctitis induced by radiotherapy in cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: patients aged older than 18 years; need for 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 who doesn't use a secure contraception method; known allergy to any ingredients of ointments; concurrent 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

Randomization will be done using random number table.

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, kilometer 18 of Farah Abad Blvd, Khazar square, Sari, Mazandaran Province

City

Sari

Postal code**Approval date**

2015-11-10, 1394/08/19

Ethics committee reference number

IR.MAZUMS.REC.94-1743

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**

The effect of proctitis on the lifestyle with a scoring system described by Kennedy et al, 2001

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**

Patient's psycho-social 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: sucralfate 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 Sari Imam Khomeini Hospital

Full name of responsible person

Sara Sai

Street address

Radiotherapy Center of the Emam Khomeini Hospital, Amir Mazandarani Blvd, Sari, Mazandaran Province, Iran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Vice chancellor for research, 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

Vice Chancellor for research of 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

Mazandaran University of Medical Sciences, Faculty of Pharmacy

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