

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of endoscopic management of anastomosis leakage in rectal cancer patient operated in colorectal surgery ward in Imam Khomeini hospital in 2022-2023

Protocol summary

Study aim

Evaluation of endoscopic management in anastomosis leakage after low anterior resection in rectal cancer patients.

Design

Non randomised, non blinded, clinical trial, designed for 10 patients who undergo low anterior resection for rectal cancer and had anastomosis leakage.

Settings and conduct

All rectal cancer patients who undergo low anterior resection and have anastomosis leakage after surgery, and don't have peritonitis, are involved. Endoscopic management for leakage includes washing with serum and brushing is done weekly or more as demanded for patients in endoscopy unit in colorectal ward of Imam Khomeini hospital.

Participants/Inclusion and exclusion criteria

Patients who undergo low anterior resection for rectal cancer and have anastomosis leakage.

Intervention groups

Colonoscopic washing and brushing of sinus formation around anastomosis leakage site

Main outcome variables

Anastomosis leakage repair; no discharge from anastomosis site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120129008861N6**

Registration date: **2023-05-04, 1402/02/14**

Registration timing: **retrospective**

Last update: **2023-05-04, 1402/02/14**

Update count: **0**

Registration date

2023-05-04, 1402/02/14

Registrant information

Name

Mohammad Reza Keramati

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1657

Email address

mr-keramati@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-26, 1401/10/05

Expected recruitment end date

2023-02-24, 1401/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of endoscopic management of anastomosis leakage in rectal cancer patient operated in colorectal surgery ward in Imam Khomeini hospital in 2022-2023

Public title

Evaluation of endoscopic management of anastomosis leakage in rectal cancer patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Anastomosis leakage Low anterior resection of rectal cancer

Exclusion criteria:

Peritonitis, Acute abdomen Patient don't accept endoscopic management

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 10

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences ethics committee

Street address

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.241

Health conditions studied

1

Description of health condition studied

Rectal cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

Repair of anastomosis leakage

Timepoint

Weekly until anastomosis leakage is repaired

Method of measurement

By colonoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: endoscopic washing with serum and brushing of fibrotic and granulation tissue

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences, Imam Khomeini Hospital

Full name of responsible person

Dr. Mohammad Reza Keramati

Street address

Imam Khomeini Hospital, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

123454567890

Phone

+98 21 6119 0000

Email

mr-keramati@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nima Rezayi

Street address

Keshavarz Blvd, Ghods St, Poursina Ave. Faculty of Medicine

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6641 8466

Fax

+98 21 6641 8466

Email

rezaei_nima@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran medical university

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

Tehran University of Medical Sciences

Full name of responsible person

Aazam Rahimi

Position

colorectal surgery fellowship

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital surgery ward, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 6119 2607

Fax

+98 21 6119 2606

Email

azamrahimi7878@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Keramati

Position

Associate Professor of Surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1657

Email

mr-keramati@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aazam rahimi

Position

fellowship of colorectal surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital surgery ward, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 6119 2607

Fax

+98 21 6119 2606

Email

azamrahimi7878@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data will be shared after blinding of datasheet.

When the data will become available and for how long

Data will be shared within 6 months after publication.

To whom data/document is available

Data will be accessible for researchers affiliated to universities

Under which criteria data/document could be used

Data can be used for further meta-analysis after permission of the person responsible for this project.

From where data/document is obtainable

Data request should be sent through email for the person responsible for this project. Dr. Mohammad Reza Keramati mr-keramati@tums.ac.ir

What processes are involved for a request to access data/document

Following the primary request, all the researchers will be informed by the responsible person and after permission the data will be shared.

Comments