

# 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**