

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of outcomes and complications between anterior repair and resection-anastomosis of small intestine for closure of loop ileostomy performed in patients underwent rectal cancer resection surgery

Protocol summary

Study aim

To compare complications after surgery in two groups of anterior repair versus resection and hand sewn anastomosis.

Design

This is a prospective, randomized, double-blind clinical trial.

Settings and conduct

This study was performed at the colorectal surgery division of department of surgery at Tehran University of Medical Sciences between September 1, 2016 and December 1, 2018.

Participants/Inclusion and exclusion criteria

Inclusion criterion: patients with history of rectal cancer underwent low anterior resection surgery with protective loop ileostomy. Exclusion criteria: immune deficiency; rectal anastomosis complications; history of abdominal surgery except rectal surgery.

Intervention groups

Intervention group A: 20 patients randomly selected and placed in the resection and anastomosis group. Proximal and distal of the intestine within the ileostomy site were resected then anastomosed. Intervention group B : 20 patients randomly selected and placed in the anterior repair group. Anterior intestinal defect within the ileostomy site was repaired.

Main outcome variables

the first day of defecation / the first day of flatus / the first day of oral feeding / post operation early complications / post operation late complications

General information

Reason for update

In this study, participants, collectors of results and analyzers, were blind to the study. Wrongly, single-blind study was entered that should be corrected to double-

blind study.

Acronym

IRCT registration information

IRCT registration number: **IRCT201703158861N2**

Registration date: **2017-05-08, 1396/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-25, 1401/04/04**

Update count: **1**

Registration date

2017-05-08, 1396/02/18

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

Tehran University of Medical Sciences

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes and complications between anterior repair and resection-anastomosis of small intestine for closure of loop ileostomy performed in patients underwent rectal cancer resection surgery

Public title

Comparison between anterior repair and resection-anastomosis of small intestine for closure of loop ileostomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a history of rectal cancer who had undergone curative low anterior resection for rectal cancer and a diverting protective loop ileostomy

Exclusion criteria:

history of immunodeficiency complications associated with rectal anastomosis, including anastomotic leakage, para-anastomotic sinuses previous abdominal operation other than rectal cancer surgery

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

patients were randomly assigned into two groups using randomly permuted blocks method. random allocation sequence was generated by the online platform www.randomization.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants, collectors of results and analyzers, were blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

6th floor, Central building of Tehran University of Medical Sciences, Ghods St., Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1234567899

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.TUMS.VCR.REC.1395.494

Health conditions studied

1

Description of health condition studied

Function of bowel

ICD-10 code

K59.9

ICD-10 code description

Functional intestinal disorder, unspecified

Primary outcomes

1

Description

the first day of defecation

Timepoint

daily up to one week

Method of measurement

question from the patient in daily ward visits

2

Description

the first day of flatus

Timepoint

daily up to one week

Method of measurement

question from the patient in daily ward visits

3

Description

the first day of oral feeding

Timepoint

daily up to one week

Method of measurement

stariting of oral diet based on surgeons decision

4

Description

post operation early complications

Timepoint

daily up to one month

Method of measurement

question from the patient in daily ward visits

5**Description**

post operation late complications

Timepoint

monthly up to 6 months

Method of measurement

question from the patient in monthly clinic visits

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group A: 20 patients randomly selected and placed in the resection and anastomosis group. Proximal and distal of the intestine within the ileostomy site were resected then anastomosed.

Category

Treatment - Surgery

2**Description**

Intervention group B : 20 patients randomly selected and placed in the anterior repair group. Anterior intestinal defect within the ileostomy site was repaired.

Category

Treatment - Surgery

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**

Research deputy, School of Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhoondzadeh

Street address

Faculty of Medicine, Poor-sina St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 6119 0000

Email

mr-keramati@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research deputy, School of Medicine, Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyed Mostafa Meshkati Yazd

Position

MD/ Resident of surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

123456789

Phone

+98 21 8860 7395

Fax

Email

mostafa.meshkati@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Keramati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 2283 3381

Fax

Email

mr-keramati@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Keramati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 2283 3381

Fax

Email

mr-keramati@razi.tums.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The result of this study will be presented in the form of an article.

When the data will become available and for how long

Information can be accessed at any time.

To whom data/document is available

All individuals.

Under which criteria data/document could be used

In scientific studies and clinical treatment of related patients.

From where data/document is obtainable

Colorectal Research Center of Imam Khomeini Hospital, Tehran University Of Medical Science. Contact the person in charge who is mentioned.

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

Contact the colorectal center of the University of Tehran or contact the person in charge who is mentioned.

Comments