

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of outcomes and complications between anterior repair, resection and hand sewn anastomosis, resection and stapled anastomosis of small intestine for reversal of loop ileostomy in patients who underwent rectal cancer resection surgery

Protocol summary

Study aim

To compare complications after surgery in three groups of anterior repair, resection and hand sewn anastomosis and resection and stapled anastomosis.

Design

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

Settings and conduct

This study will be performed at the colorectal surgery division of department of surgery at Tehran University of Medical Sciences between January 27, 2023 and August 23, 2023.

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.

Intervention groups

Intervention group A: 32 patients randomly selected and placed in the resection and hand sewn anastomosis group. Proximal and distal of the intestine within the ileostomy site were resected then anastomosed with hand sewn. Intervention group B : 32 patients randomly selected and placed in the anterior repair group. Anterior intestinal defect within the ileostomy site was repaired. Intervention group C: 32 patients randomly selected and placed in the resection and stapled anastomosis group. Proximal and distal of the intestine within the ileostomy site were resected then anastomosed with stapler.

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

Acronym

IRCT registration information

IRCT registration number: **IRCT20120129008861N5**

Registration date: **2023-01-15, 1401/10/25**

Registration timing: **prospective**

Last update: **2023-01-15, 1401/10/25**

Update count: **0**

Registration date

2023-01-15, 1401/10/25

Registrant information

Name

Mohammad Reza Keramati

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-27, 1401/11/07

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes and complications between anterior repair, resection and hand sewn anastomosis, resection and stapled anastomosis of small intestine for reversal of loop ileostomy in patients who underwent rectal cancer resection surgery

Public title

Comparison between anterior repair, resection and hand sewn-anastomosis and resection and stapled 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

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

patients were randomly assigned into three 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, Investigator and Outcome assessor, were blind to the study. Before the surgery, the patients are randomly divided into three groups, which the patients and investigators do not know about it, and then the surgeon in the operating room is informed about the type of surgery of each patient, and the surgery is performed, and then the patients are transferred to the surgery ward. The patients are visited by the another surgeon (investigator and outcome assessor) who is blind with the type of surgery of each patient and the information and data of the patients are collected and then the information is sent to the analyzer team.

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, research ethics committees of Imam Khomeini Hospital complex

Street address

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

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Province

Tehran

Postal code

1234567899

Approval date

2022-12-20, 1401/09/29

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.261

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: 32 patients randomly select and place in the resection and anastomosis group. Proximal and distal of the intestine within the ileostomy site are resected then hand sewn anastomosis will be done.

Category

Treatment - Surgery

2

Description

Intervention group B : 32 patients randomly select and place in the anterior repair group. Anterior intestinal defect within the ileostomy site will be repaired.

Category

Treatment - Surgery

3

Description

Intervention group C: 32 patients randomly select and place in the resection and anastomosis group. Proximal and distal of the intestine within the ileostomy site are resected then anastomosis will be done by the stapler.

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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhoondzadeh

Street address

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

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Grant name

Grant code / Reference number

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

No

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

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/general surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Mohammad Reza Keramati

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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