

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Clinical outcomes of colonic J-pouch, straight colorectal and side-to-end anastomosis procedures in rectal cancer

Protocol summary

Study aim

The aim of this study is to compare the performance and clinical outcome of three methods of colorectal anastomosis, Straight, Side to end, and J-Pouch methods in patients with colorectal cancer.

Design

This randomized, single-blind, parallel, clinical trial was performed during two years from March 2017 to September 2018 in Imam Khomeini Hospital (Sari, Iran) on 60 colorectal cancer patients. Sixty patients were randomly divided into three groups by randomly drawing sealed envelopes, using a computer-based table of randomization by a surgical assistant.

Settings and conduct

The demographic and clinical data were extracted from medical records and patients were followed up to evaluate functional characteristics of anastomotic methods. The participants, observer and data analyzer were not familiar with three types of anastomosis surgery in this study. However, the main researcher (surgeon) was informed about the groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria were as follows: all patients with 1) rectal adenocarcinoma, located 4 to 12 cm from anal verge who referring to Imam Khomeini Hospital in Sari from March 2017 to September 2018, 2) Complete medical documents 3) Possible oncological and functional sphincter preserving. The exclusion criteria were as follows: 1) Patients with incomplete documents, 2) continued treatment in other centers, 3) unavailable information 4) unknown tumor stage.

Intervention groups

Group A was undergone anterior resection with straight colorectal anastomosis (SA). group B was undergone colonic J-pouch (CJP) anastomosis. group C was undergone side-to-end colorectal anastomosis.

Main outcome variables

Demographic data (age, sex), Tumor characteristics were extracted from patients' documents and recorded in a

questionnaire. Clinical performance evaluation was performed on the seventh day, the second month, and the sixth month.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141218020364N12**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **retrospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Mohhammad Yasin Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3839 1385

Email address

karamiy@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-01, 1395/12/11

Expected recruitment end date

2018-12-01, 1397/09/10

Actual recruitment start date

2017-04-04, 1396/01/15

Actual recruitment end date

2018-08-01, 1397/05/10

Trial completion date

2019-04-21, 1398/02/01

Scientific title

Clinical outcomes of colonic J-pouch, straight colorectal and side-to-end anastomosis procedures in rectal cancer

Public title

Different anastomosis procedures in rectal cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Rectal adenocarcinoma, located 4 to 12 cm from anal verge Complete medical documents Possible oncological and functional sphincter preserving

Exclusion criteria:

Patients with incomplete documents, Continued treatment in other centers, Unavailable information Unknown tumor stage

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization of individual by randomly drawing sealed envelopes, using a computer-based table of randomization by a surgical assistant

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, the participants were not familiar with three types of anastomosis surgery in this study. In addition, the observer, who completed the questionnaire, was not familiar with the groups. Similarly, the data analyzer did not know the study groups. However, the main researcher (surgeon) was informed about the groups, and all surgical procedures were performed by the same surgeon. The safety and data monitoring committee was also informed about the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Valie Asr highway

City

Sari

Province

Mazandaran

Postal code

984815733971

Approval date

2018-06-27, 1397/04/06

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.018

Health conditions studied

1

Description of health condition studied

Colon Cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

2

Description of health condition studied

Rectal Cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

Surgery period

Timepoint

onset to end of anesthesia

Method of measurement

Minute

2

Description

Hospital Stay

Timepoint

Discharge Time

Method of measurement

day

3

Description

Blood Loss

Timepoint

End of surgery

Method of measurement

CC

Secondary outcomes

1

Description

Defecation Frequency

Timepoint

Six months

Method of measurement

Normal, Frequently, More than 6 times

2

Description

Stool consistency

Timepoint

6 Month

Method of measurement

Normal, Loose, Liquid

3

Description

Stool Leakage

Timepoint

6 month

Method of measurement

No, Diarrhea, Always

4

Description

Sense of urgency

Timepoint

6 month

Method of measurement

Normal , Short

5

Description

Difficult defecation

Timepoint

6 month

Method of measurement

Yes, No

Intervention groups

1

Description

Intervention group1: Coloanal End to End Anastomosis

Category

Treatment - Surgery

2

Description

Intervention group 2: Side to End Anastomosis

Category

Treatment - Surgery

3

Description

Intervention group 3: J poach coloanal anastomosis

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mina Alvandipoor

Street address

Razi Ave

City

Sari

Province

Mazandaran

Postal code

984816633131

Phone

+98 11 3336 1700

Email

Minaalvh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Mazandaran University of Medical Sciences, Joybar
three ways

City

sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3324 9815

Email
saeidimajid@yahoo.com

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

Title of funding source
Sari 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
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Yasin Karami

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Faghighi Hospital

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

