

# 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 scientific inquiries

### Contact

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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

