

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparative study of functional and quality of life outcomes in patients with very low rectal cancer undergoing an inter sphincter resection with and without appendicostomy

#### Protocol summary

##### Study aim

Determine the efficacy of Appendicostomy in reducing the psychological complications, gas incontinence and satisfaction of patients undergoing very low rectal resection surgery.

##### Design

Two arm parallel group randomized controlled clinical trial

##### Settings and conduct

Patients with rectal cancer are admitted to the surgery department of Imam Khomeini Hospital in Sari. Patients will be divided into two groups using random numbers. A group undergoing very low anterior rectal resection without appendicostomy, and in the second group very low anterior rectal resection is performed with appendicostomy.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with a diagnosis of rectal cancer by a pathologist faculty member based on World Health Organization criteria. Includes operable stage 1 low and very low rectal cancer after neoadjuvant therapy. Exclusion criteria: heart failure, mental retardation, diabetes, high dose corticosteroid therapy and other diseases that have the effect on wound healing.

##### Intervention groups

Patients undergoing very low Anterior resection with or without appendicostomy

##### Main outcome variables

Improvement of functional results, control of gas incontinence and quality of life in patients with rectal cancer

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20141218020364N9**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

#### Registration date

2018-09-22, 1397/06/31

#### 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

2016-12-21, 1395/10/01

#### Expected recruitment end date

2017-12-22, 1396/10/01

#### Actual recruitment start date

2017-01-09, 1395/10/20

#### Actual recruitment end date

2018-02-09, 1396/11/20

#### Trial completion date

2019-02-20, 1397/12/01

#### Scientific title

Comparative study of functional and quality of life outcomes in patients with very low rectal cancer

undergoing an inter sphincter resection with and without appendicostomy

## Public title

Efficacy of Appendicostomy in reducing the psychological complications of rectal cancer patients undergoing inter-sphincter very low anterior resection

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Stage 1( T1 ,T2 till muscularis propria) of very low rectal cancer which approved by an endosonography survey and pathologist faculty member based on World Health Organization criteria, those who had neoadjuvant chemotherapy.

### Exclusion criteria:

Chronic Pulmonary disease Heart failure diabetes Mental Retardation High dose Corticosteroid therapy Immune deficiency Poor Follow up condition other diseases that have effect on wound healing.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **50**

Actual sample size reached: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple individual randomization using the table of random numbers

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran of Medical Sciences

##### Street address

Tohid Alley, Shahband Ave

##### City

sari

##### Province

Mazandaran

##### Postal code

4815696869

##### Approval date

2016-11-02, 1395/08/12

##### Ethics committee reference number

IR.MAZUMS.REC.95.2350

## Health conditions studied

### 1

#### Description of health condition studied

Rectal cancer

#### ICD-10 code

C21.8

#### ICD-10 code description

Malignant neoplasm of overlapping sites of rectum, anus and anal canal

## Primary outcomes

### 1

#### Description

Quality of life score of EORTC-QLQ-C30 (The European organization for research and treatment of cancer quality of life questionnaire)

#### Timepoint

3, 6, 12 months after surgery

#### Method of measurement

EORTC-QLQ-C30(The European organization for research and treatment of cancer quality of life questionnaire)

### 2

#### Description

Evaluation of continence in Wexner questionnaire

#### Timepoint

3, 6, 12 months after surgery

#### Method of measurement

Wexner questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Appendicostomy: Surgery is done in two steps.first, after the release of the descending colon, the inferior mesenteric artery and vein are high lighted. The sigmoid colon is removed from the middle portion. Then the perineal phase is done and throws intersphincter groove complex of ithe ntrenal anal sphincter and the rectum and distal sigmoid are resect then end to end coloanal anastomosis using PDS 3.0 will be done. At the same time, an appendicostomy is inserted for the patient.T o do this, the appendix is

dissected and the longitudinal incision of the distal appendices is done, then, in right lower quadrant skin U shape incision is performed and anti mesenteric edges are sutured to the skin with 4-0 absorbable. A small catheter is placed in the appendicostomy for a week and the first antegrade enema with one litre of water is done. The necessary care and method of using appendicostomy is given to patients before discharge.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: without appnndicostomy: first, after the release of the descending colon, the inferior mesenteric artery and vein are high lighted. The sigmoid colon is removed from the middle portion. Then the perineal phase is done and throws intersphincter groove complex of the internal anal sphincter and the rectum and distal sigmoid are resect then end to end coloanal anastomosis using PDS 3.0 will be done.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Mina Alvandipour

##### Street address

Amir Mazandarani Ave.

##### City

sari

##### Province

Mazandaran

##### Postal code

4416633131

##### Phone

+98 11 3335 0670

##### Email

yasinkarami@gmail.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

General Surgeon

##### Latest degree

Specialist

##### Other areas of specialty/work

General Surgery

##### Street address

zand ave

##### City

shiraz

##### Province

Fars

##### Postal code

7441756965

##### Phone

+98 917 180 0710

##### Email

karamiy@sums.ac.ir

## Person responsible for scientific 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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**Person responsible for updating data****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

**Street address**

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**Province**

Fars

**Postal code**

7441756965

**Phone**

+98 917 180 0710

**Email**

karamiy@sums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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

**Title and more details about the data/document**

The questionnaire of patients

**When the data will become available and for how long**

At the same as the results

**To whom data/document is available**

University researchers

**Under which criteria data/document could be used**

...

**From where data/document is obtainable**

Sari Imam Khomeini Hospital

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

...

**Comments**