Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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 mascularis properia) of very low rectal cancer which approved by an endosonography survey and pathologist faculty member based on World Health Organization criteria, those who had neoadjuant 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 nternal 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
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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
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Mazandaran
Postal code
4815733971
Phone
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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Person responsible for updating data

Contact
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Shiraz University of Medical Sciences
Full name of responsible person
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Position
Assistant professor
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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