Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of appendicostomy on functional outcomes and quality of life in patients undergoing surgery abdominoperineal resection due to rectal cancer

Protocol summary

Study aim

Determine the efficacy of Appendicostomy in reducing the psychological complications of patients undergoing APR (Abdominoperineal resection) surgery Determine the efficacy of Appendicostomy in gas incontinence of patients undergoing APR surgery Determine the efficacy of Appendicostomy in satisfaction of patients undergoing APR surgery

Design

Two arm parallel group randomized controlled concurrent 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 abdominoprenal resection without appendicostomy, and in second group abdominoprenal 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 low and very low rectal cancer, or those with a high stage rectal cancer who after neoadjuant therapy are down stage and operable. Exclusion criteria: heart failure, mental retardation, diabetes, high dose corticosteroid therapy and other deseases that have effect on wound healing.

Intervention groups

Patients undergoing abdominoperineal 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: **IRCT20180514039651N1**
Registration date: **2018-06-13, 1397/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-13, 1397/03/23**
Update count: **0**

Registration date

2018-06-13, 1397/03/23

Registrant information

Name

Amin Salimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3339 1126

Email address

dr.aminsalimi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-31, 1396/10/10

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of appendicostomy on functional outcomes and quality of life in patients undergoing surgery abdominoperineal resection due to rectal cancer

Public title
Appendicostomy in rectal cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Rectal adenocarcinoma confirmed by pathology Patients with operable low or very low Rectal cancer or patients with operable high stage Rectal cancer after neoadjuvant therapy
Exclusion criteria:
Heart failure Mental retardation Diabetes High dose Corticosteroid therapy Immunodeficiency Cases that have delay in wound healing
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization
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 Sari University of Medical Sciences
Street address
Tohid Alley, Shahband Ave.,
City
Sari
Province
Mazandaran
Postal code
4815696869

Approval date
2018-04-22, 1397/02/02
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.1150

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 questinnaire
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 disending colon, the inferior mesenteric artery and vein are high ligated. The sigmoid colon is removed from the middle portion. Then the perineal phase is done and The complex of anal sphincter and the rectum and distal sigmoid are resected and left side colostomy are inserted and perineal incision are closed. At the same time, an appendicectomy is inserted for patient.To do this, the appendix is dissected and the longitudinal insision of the distal appendices is done,then in right lower quadrant skin U shape insision is performed and anti mesenteric edges are sutured to the skin with 4-0 absorbable. A small catheter is placed in

the appendicectomy for a week and the first antegrade enema with one liter of water is done. The necessary care and method of using appendicectomy is given to patients before discharge.

Category

Treatment - Surgery

2

Description

Control group: without appendicostomy: First, after the release of the disending colon, the inferior mesenteric artery and vein are high ligated. The sigmoid colon is removed from the middle portion. Then the perineal phase is done and The complex of anal sphincter and the rectum and distal sigmoid are resected and left side colostomy are inserted and perineal incision are closed.

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

dr.aminsalimi@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

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4815733971

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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

Mazandaran University of Medical Sciences

Full name of responsible person

Amin Salimi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Shahband Ave., Tohid all.

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Amin Salimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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 questionnaie 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