Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the results of early ileostomy closure in patients with rectal cancer (stage 2,3) who underwent LAR surgery compared to the usual method (delayed closure after the end of chemotherapy adjuvant)

Protocol summary

Study aim

Determination of the results of early ostomy closure in patients with stage2,3 rectal cancer who underwent LAR.

Design

A clinical trial with a control group, with parallel, randomized groups, on 100 patients

Settings and conduct

Study place: In the surgical ward of Sinai Hospital in Tehran during 2015 and 2016. According to the calculation, patients with stage 2,3 rectal cancer who have received neoadjuvant radiotherapy after L.A.R and implantation of protective ileostomy will be studied.

Participants/Inclusion and exclusion criteria

Including criteria: (1) Patients with locally advanced rectal cancer (stage 2,3) (2) Receive neoadjuvant radiotherapy. (3) L.A.R and implantation of protective ileostomy (4) Satisfaction with premature ostomy closure. Excluding Criteria: 1- Leak evidence of anastomosis in the study of water-soluble contrast 2- Do not start Adj chemotherapy during 2-4 weeks after the first surgery 3- Dissatisfaction with ostomy closure 4- Occurrence of systemic complications not related to postoperative underlying disease including PTE, MI, CVA 5- Concomitant diseases such as diabetes, heart and lung failure

Intervention groups

Group A includes patients who meet the inclusion criteria after receiving the second dose of adjuvant chemotherapy and a week of rest after that (6 weeks of surgery) to close the ostomy, be hospitalized and undergo surgery. Group B will also include eligible patients. In this group, ostomy adjuvant chemotherapy will be closed after the end of 6 courses. The evaluation of these patients during hospitalization and after discharge will be similar to the previous group.

Main outcome variables

Length of second operation, ostomy complications, Stage, type of operation, time interval between second operation and first operation, CEA, anastomotic complications

General information

Reason for update

Continue the patient recruitment process and increase the sample size and complete the information

Acronym

IRCT registration information

IRCT registration number: **IRCT20201113049373N1**
Registration date: **2021-01-02, 1399/10/13**
Registration timing: **retrospective**

Last update: **2021-06-15, 1400/03/25**
Update count: **1**

Registration date

2021-01-02, 1399/10/13

Registrant information

Name

Ehsan Rahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4443 5556

Email address

dr.rahimpour83@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date
2016-03-20, 1395/01/01
Actual recruitment end date
2019-09-21, 1398/06/30
Trial completion date
2020-01-20, 1398/10/30

Scientific title
Evaluation of the results of early ileostomy closure in patients with rectal cancer (stage 2,3) who underwent LAR surgery compared to the usual method (delayed closure after the end of chemotherapy adjuvant)

Public title
Early closure ileostomy in patients with rectal cancer (stage 2,3) who have undergone LAR surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
(1) Patients with locally advanced rectal cancer (stage 2,3)(2) Receive neoadjuvant radiotherapy.(3) L.A.R and implantation of protective ileostomy(4) Satisfaction with premature ostomy closure
Exclusion criteria:
1- Leak evidence of anastomosis in the study of water-soluble contrast 2- Do not start Adj chemotherapy during 2-4 weeks after the first surgery 3- Dissatisfaction with ostomy closure 4- Occurrence of systemic complications not related to postoperative underlying disease including PTE, MI, CVA 5- Concomitant diseases such as diabetes, heart and lung failure
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Actual sample size reached: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on blockchain of quadruple numbers For randomization, the variable blocks method was used, which was due to the ease of execution and balance in the number of groups. In this way, the samples were divided into A and B and for the four blocks, six modes were created and based on the number of samples, the cards were replaced. AABB ABAB BBAA BABA ABBA BAAB
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 Tehran University of Medical Sciences
Street address
Imam Khomeini St., 30 Tir St., Sina Hospital
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2016-05-21, 1395/03/01
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3145

Health conditions studied

1

Description of health condition studied
Rectal cancer
ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

Primary outcomes

1

Description
Complications of early ileostomy closure
Timepoint
1،2،3،4،5،14،30،90،180 day
Method of measurement
questionnaire

2

Description
Survival of patients
Timepoint
3,6,12 month
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group A includes patients who meet the inclusion criteria after receiving the second dose of adjuvant chemotherapy and two week of rest after about (8weeks of surgery) to close the ostomy, be hospitalized and undergo surgery.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
ehsan rahimpour
Street address
Imam Khomeini St., 30 Tir St., Sina Hospital
City
Tehran
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1136746911
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+98 21 6312 0000
Email
dr.rahimpour83@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Imam Khomeini St., 30 Tir St., Sina Hospital
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Ehsan Rahimpour
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person

Ehsan Rahimpour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not all data can be shared

When the data will become available and for how long

Access period 6 months after printing

To whom data/document is available

All people

Under which criteria data/document could be used

All analyzes are possible on the data.

From where data/document is obtainable

dr.rahimpour83@gmail.com 00989123705047

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

The request will be sent within about 2 weeks.

Comments