Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the results of ghost ileostomy versus protective ileostomy in low anterior resection surgery, in rectal cancer undergoing neoadjuvant chemo-radiotherapy.

Protocol summary

Study aim
To compare anastomotic leakage in two groups of patients with and without ileostmy

Design
Randomized clinical trial, no blindness, with control group in 2 groups of 40 rectal cancer patients (total of 80) with and without ghost ileostomy. Randomized with EXCEl software.

Settings and conduct
Randomized clinical double blind trial 80 rectal cancer patients Admitted In Emam khomeini hospital in Tehran, treated with surgery and doubled blinded with Excel software into two groups of 1- with ghost ileostomy 2- without ghost ileostomy

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients undergone conventional chemoradiotherapy- anastomosis locations is 5 cm above the anal verge. exclusion criteria: adhesion; positive leak test; incomplete doughnut; obstruction or peritonitis- diabetes; age>75; immune suppressed.

Intervention groups
Intervention group: a loop of ileum is elevated under the fascia with a silk thread and the ghost ileostomy is made. Control group: ileostomy is matured in a classic method of surgery.

Main outcome variables
Anastomosis leakage; re exploration of abdomen; readmission; mortality; days of hospitalization.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120129008861N3**
Registration date: **2021-01-10, 1399/10/21**
Registration timing: **retrospective**
Last update: **2021-01-10, 1399/10/21**
Update count: **0**

Registration date
2021-01-10, 1399/10/21

Registrant information

Name
Mohammad Reza Keramati

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-21, 1398/03/31

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
2019-08-22, 1398/05/31

Actual recruitment end date
2020-09-21, 1399/06/31

Trial completion date
2020-11-20, 1399/08/30

Scientific title
Comparison of the results of ghost ileostomy versus protective ileostomy in low anterior resection surgery, in rectal cancer undergoing neoadjuvant chemo-radiotherapy.

Public title
Comparison of the results of ghost ileostomy versus

protective ileostomy in rectal cancer.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Rectal cancer patients History of previous neoadjuvant chemoradiotherapy tumor located more than 5 cm from anal verge candidate for low anterior resection surgery

Exclusion criteria:

difficult surgery or excessive bleeding immune suppression , steroid use , malnutrition obstruction or peritonitis ASA score >3 BMI>30 Diabetes Age >75 years incomplete doughnut at the end of surgery positive air leak test of anastomosis

Age

To **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Randomization; Random unit: Individual; Randomization tool: Excel; Randomization Output: 1=With Ghost Ileostomy 2=Without Ghost Ileostomy

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

Tehran university of medical sciences ethics committee

Street address

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2018-04-22, 1397/02/02

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.020

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

anastomosis leakage

Timepoint

anastomosis leakage 1week,1,3,6 months

Method of measurement

colonoscopy

2

Description

Abdomen re-explorization

Timepoint

Anytime the abdomen is re-explored for surgery

Method of measurement

Observation

3

Description

Mortality

Timepoint

Time of death one year from surgery

Method of measurement

Observation

4

Description

Re-admission

Timepoint

Date of re-admission 3 months after surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description
Control group: protective ileostomy group
Category
Treatment - Surgery

2

Description
Intervention group: ghost ileostomy group
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohamad Reza Keramati
Street address
End of Keshavarz Blvd,Tehran,Iran
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Sponsors / Funding sources

1

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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
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Marzieh Ghanbari
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data will be shared after blinding of datasheet.
When the data will become available and for how long
Data will be shared within 6 months after publication.
To whom data/document is available
Data will be accessible for researchers affiliated to universities.
Under which criteria data/document could be used
Data can be used for further meta-analysis after permission of the person responsible for this project.
From where data/document is obtainable
Data request should be sent through email for the person responsible for this project. Dr. Mohammad Reza Keramati mr-keramati@tums.ac.ir
What processes are involved for a request to access data/document
Following the primary request, all the researchers will be informed by the responsible person and after permission the data will be shared.
Comments