

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 ileostomy

##### 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

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6658 1657

###### Email address

mr-keramati@razi.tums.ac.ir

##### 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733141

#### Phone

+98 21 6119

#### Email

mr-keramati@razi.tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohamad Reza Keramati

#### Street address

Poursina street, Qods street, Enqelab square, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1417613151

#### Phone

+98 21 6111 3411

#### Email

razi@tums.ac.ir

#### 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

Marzieh Ghanbari

#### Position

MD / Resident of Surgery

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Surgery

#### Street address

end of Keshavarz avenue, Gharib st, Imam khomeini hospital

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۱۹۷۳۳۱۴۱

#### Phone

+98 21 6119

#### Email

ghanbari.mrz@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohammad Reza Keramati

#### Position

Associate Professor of Surgery

#### Latest degree

Subspecialist

#### Other areas of specialty/work

General Surgery

#### Street address

Imam Khomeini hospital, Keshavarz blvd.

#### City

Tehran

#### Province

Tehran

**Postal code**  
1419733141  
**Phone**  
+98 21 6658 1657  
**Email**  
mr-keramati@tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohamad Reza Keramati  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Imam Khomeini hospital, Keshavarz blvd.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1419733141  
**Phone**  
+98 21 6658 1657  
**Email**  
mr-keramati@tums.ac.ir

## 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