

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of wound complication in anal area between two methods of primary repair and Limburg flap repair in abdominoperineal resection in rectal cancer

#### Protocol summary

##### Study aim

Comparison of wound complication in anal area between two methods of primary repair and Limburg flap repair in abdominoperineal resection in rectal cancer

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. A block method was used for randomization.

##### Settings and conduct

This study was designed and implemented in Imam Khomeini Sari Medical Education Center affiliated with Mazandaran University of Medical Sciences as a randomized clinical trial with a double-blind control group. Patients were randomly divided into two groups. All patients underwent Abdominoperineal Resection. The type of anal skin repair method was different in two groups. Primary group or initial repair of anal wound = in this method, the anal area was performed as a primary repair and in the middle line. Limberg flap group = repair by flap method In this method, the anal area was repaired by Limberg flap method.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 20 to 90 years old with rectal cancer that underwent abdominoperineal resection. Exclusion criteria: no follow up

##### Intervention groups

Patients were randomly divided into two groups. All patients underwent Abdominoperineal Resection. The type of anal skin repair method was different in two groups. control group or initial repair of anal wound = in this method, the anal area was performed as a primary repair and in the middle line. Limberg flap group = repair by flap method In this method, the anal area was repaired by Limberg flap method.

##### Main outcome variables

Occurrence of infection, discharge, bleeding from the anal wound site, anal wound healing time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230809059096N1**

Registration date: **2024-01-30, 1402/11/10**

Registration timing: **retrospective**

Last update: **2024-01-30, 1402/11/10**

Update count: **0**

##### Registration date

2024-01-30, 1402/11/10

##### Registrant information

##### Name

Mohammad Javad Najafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 223 5772

##### Email address

mjnajafi@rocketmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

2020-02-01, 1398/11/12

##### Actual recruitment end date

2021-05-01, 1400/02/11

##### Trial completion date

2021-05-01, 1400/02/11

## Scientific title

Comparison of wound complication in anal area between two methods of primary repair and Limburg flap repair in abdominoperineal resection in rectal cancer

## Public title

Limberg flap repair in wound healing of anal surgery site in Abdominoperineal Resection surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age between 20 to 90 Rectum cancer Abdominoperineal resection

### Exclusion criteria:

No follow up

## Age

From **20 years** old to **90 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **50**

Actual sample size reached: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

We use the block randomization method to randomize subjects into groups that result in equal sample sizes. At the beginning of the randomization process, we randomly choose one of the following blocks by randomly throwing the dice and divide the rest of the samples into 2 groups according to the order of the samples. A: intervention and B: control B A B A 2) B B A A 1) B A A B 4) A B B A 3) A A B B 6) A B A B 5)

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Based on the classification, people entered and will receive the planned treatment and intervention based on their specific group, and the results are recorded separately and based on coding. Patients and data analyzers are unaware and blinded to it, and only the surgical team is aware of the type of intervention. At the end of the study, the analyst uses the codes of the groups and the coding instructions to access the nature of the groups for analysis and conclusions.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Imam Khomeini Hospital ethics committee

##### Street address

Razi street, Sari, Mazandaran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816633131

#### Approval date

2019-07-16, 1398/04/25

#### Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.084

## Health conditions studied

### 1

#### Description of health condition studied

Malignant neoplasm of rectum

#### ICD-10 code

C20

#### ICD-10 code description

Malignant neoplasm of rectum

## Primary outcomes

### 1

#### Description

Incidence of infection

#### Timepoint

One day, 7 days, 14 days, one month after the operation

#### Method of measurement

Lab data and physical exam

### 2

#### Description

Bleeding

#### Timepoint

One day, 7 days after the operation

#### Method of measurement

Lab data and physical exam

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Flap repair in the anal area using the Limberg flap method

**Category**

Treatment - Surgery

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Mina Alvandipour

**Street address**

Razi street, Sari, Mazandaran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 11 3336 1700

**Fax**

+98 11 3336 1700

**Email**

Minaalvh@yahoo.com

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Pedram Ebrahim Nejhad

**Street address**Deputy of research and technology, Moalem sq. Sari,  
Mazandaran province**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3323 7230

**Email**

pajhooheshi@mazums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mohammad Javad Najafi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Razi Street, Sari, Mazandran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 911 223 5772

**Email**

mjnajafi@rocketmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammad Javad Najafi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Amir-e-Mazandarani Street, Sari, Mazandaran, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 911 223 5772

**Fax****Email**

mjnajafi@rocketmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammad Javad Najafi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Amir-e-Mazandarani Street, Sari, Mazandaran, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 911 223 5772

**Fax****Email**

mjnajafi@rocketmail.com

## 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**

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**

Only part of the data, such as information about the main outcome or the like, can be shared.

**When the data will become available and for how long**

Start of access period 6 months after printing results

**To whom data/document is available**

It will be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Use of data to supplement research on anal wound repair using the Limburg flap method

**From where data/document is obtainable**

Contact the author of the article responsible for the research project data. Dr mohammad Javad Najafi E-mail: mjnajafi@rocketmail.com

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

Contact the author of the article responsible for the research project data. Specify the type of results requested.

**Comments**