

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 centers1**Recruitment center****Name of recruitment center**

Imam Khomeini hospital

Full name of responsible person

Mina Alvandipour

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Razi street, Sari, Mazandaran

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahim Nejhad

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

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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

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

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

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Person responsible for updating data

Contact

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Position

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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

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