

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the amount of identified lymph nodes involved in the resected sample of rectal cancer before and after injection of methylene blue in the main artery of the sample

Protocol summary

Study aim

Determining the average number of identified lymph nodes involved in the resected sample of rectal cancer by injecting methylene blue in the main artery of the sample

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, on 63 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria was age between 18 to 80 and rectum cancer. Exclusion criteria was Massive and invasive tumors that require a special technique for resection, neoadjuvant therapy, metastasis and inflammatory bowel disease.

Intervention groups

The inferior mesenteric arteries of 33 specimens were cannulated with a standard 17-20-G iv-catheter by the surgeon who is using this technique in order to check the integrity of the total mesorectal dissection. After that, the arteries were filled with 30 ml of methylene blue solution (15 mg diluted with 0.9% saline; ratio 1:1).and then specimen refer to pathology laboratory.

Main outcome variables

Determining the average number of identified lymph nodes involved in the resected sample of rectal cancer by injecting methylene blue in the main artery of the sample

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230809059096N2**

Registration date: **2024-02-17, 1402/11/28**

Registration timing: **retrospective**

Last update: **2024-02-17, 1402/11/28**

Update count: **0**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name

Mohammad Javad Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 911 223 5772

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mjnajafi@rocketmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

2019-03-20, 1397/12/29

Actual recruitment end date

2021-03-19, 1399/12/29

Trial completion date

2021-04-20, 1400/01/31

Scientific title

Comparison of the amount of identified lymph nodes involved in the resected sample of rectal cancer before and after injection of methylene blue in the main artery of the sample

Public title

Enhancing lymph node detection in rectal specimens:
The role of Methylene Blue arterial injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 80 Rectum cancer

Exclusion criteria:

Massive and invasive tumors that require a special technique for resection Neoadjuvant therapy Metastasis Inflammatory bowel disease

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **63**

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, care providers 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

2018-06-30, 1397/04/09

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.2692

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

Determining the average number of identified lymph nodes involved in the resected sample of rectal cancer by injecting methylene blue in the main artery of the sample

Timepoint

15 days

Method of measurement

pathology

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The inferior mesenteric arteries of 33 specimens were cannulated with a standard 17-20-G iv-catheter by the surgeon who is using this technique in order to check the integrity of the total mesorectal

dissection. After that, the arteries were filled with 30 ml of methylene blue solution (15 mg diluted with 0.9% saline; ratio 1:1).and then specimen refer to pathology laboratory.

Category

Treatment - Surgery

2**Description**

Control group: Total mesorectal dissection performed for control group with out any arterial injection

Category

Other

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

Imam Khomeini hospital

Full name of responsible person

Mina Alvandipour

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

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahim Nejjad

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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

Mina Alvandipour

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Colorectal Surgery

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

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

Medical doctor

Other areas of specialty/work

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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 complement research on the Methylene blue injection in artery of rectal specimen for lymph node identifying

From where data/document is obtainable

Contact the author of the article responsible for the research project data.

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