

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of the effect of adrenalized methylene blue and adrenalized Marcaine in pain relief after haemorrhoidectomy

Protocol summary

Study aim

Comparison of the effect of adrenalized methylene blue and adrenalized Marcaine in pain relief after haemorrhoidectomy

Design

This study will be performed as a randomized clinical trial (6 blocks), single-blind, without control group, with parallel groups and in phase 2-3 with the participation of 100 patients after hemorrhoidectomy.

Settings and conduct

This study will be performed with the participation of 100 candidates for hemorrhoidectomy in the operating room of Imam Reza Hospital (Tabriz University of Medical Sciences). For patients, methylene blue adrenaline and adrenaline marcaine will be used after surgery. The data analyzer will be unaware of the grouping of patients and will be blind during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hemorrhoidectomy surgery and consent to participate in the study and Exclusion criteria: Patients with drug addiction, patients with anal infection, patients with irritable bowel syndrome and patients with preanal fistula.

Intervention groups

In this randomized clinical trial study, 100 patients will be divided into two groups. Immediately after surgery, adrenalized methylene blue will be used for patients in the first group and adrenalized Marcaine will be used for patients in the second group to control their pain, and their rejection rate will be compared during the first 12 hours after surgery.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N27**

Registration date: **2022-04-15, 1401/01/26**

Registration timing: **prospective**

Last update: **2022-04-15, 1401/01/26**

Update count: **0**

Registration date

2022-04-15, 1401/01/26

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of adrenalized methylene blue and adrenalized Marcaine in pain relief after haemorrhoidectomy

Public title

Adrenalized methylene blue and adrenalized Marcaine in pain relief after haemorrhoidectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Candidate for hemorrhoidectomy surgery Satisfaction to participate in the study
Exclusion criteria:
 Patients with drug addiction Patients with anal infection
 Patients with irritable bowel syndrome Patients with perianal fistula

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block random division method (4 blocks) is used. One of the study partners, for whom no blinding was performed, named the method of treatment of adrenalized methylene blue with the letter A and the method of treatment of adrenalized marcaine with the letter B. The researcher then distributes packages A and B among the patients referred to participate in the study by block random division method (4). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size. To make a random sequence, we give possible blocks (6 blocks) from one to 6 numbers. Depending on the sample size, any number of 4 blocks that are needed will be used. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined.

Blinding (investigator's opinion)
Single blinded

Blinding description
The statistical consultant of this project will be unaware of the type of grouping of participants; The final results will be delivered to the statistical consultant. As the statistical consultant will not be in the process of grouping the participants; Therefore, he is blind during the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2022-04-06, 1401/01/17

Ethics committee reference number

IR.TBZMED.REC.1401.016

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and after intervention for twelve hours (once every hour)

Method of measurement

VAS pain intensity measuring instrument

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fifty patients will be included in this study after random allocation. After surgery,adrenalinez methylene blue (manufactured by Obaidi) will be injected into the operated area. Pain intensity will be measured for 12 hours after surgery using a VAS instrument.

Category

Treatment - Drugs

2

Description

Intervention group: Fifty patients will be included in this study after random allocation. After the surgery, adrenalinez maraine (made by Obaidi company) will be injected in the operated area. Pain intensity will be measured for 12 hours after surgery using a VAS instrument.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ramin Azhoogh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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Shahabi_p@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Dashti

Position

Resident Of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Ramin Azhogh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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