Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of intrasphincteric botox injection during hemorrhoidopexy with stapler on postoperative clinical outcomes of a double-blind clinical trial study

Protocol summary

Study aim

The effect of intrasphenobarbital botulinum toxin injection during hemorrhoidopexy on postoperative clinical outcomes.

Design

A controlled, double-blind, randomized, phase3 clinical trial with parallel groups on 68 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This study is designed as a prospective, double-blind clinical trial, and placebo (normal saline) and Botox will be drawn into a syringe and prepared by a surgeon's assistant at Imam Khomeini Hospital in Sari and Shafa Hospital in Sari in 1404. Due to the type of study design, patients and the attending physicians conducting the study will not be aware of the intervention performed on the patients (Botox or placebo), and only the primary analysts of the study will be aware of the grouping of participants in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age with symptomatic grade 3 or 4 hemorrhoids who have an indication for hemorrhoidectomy will be included in the study. Exclusion criteria: Patients with inflammatory bowel disease, fistula, fissure, and history of previous surgery in the anal area, dermatitis, proctitis, pregnancy, and severe cardiovascular or respiratory diseases will be excluded from the study.

Intervention groups

Intervention group: Botox solution manufactured by Masoon Darou Company from Iran in an amount of 0.4 ml, injected at the site of surgery. Control group: Placebo manufactured by Masoon Darou Company from Iran in an amount of 0.4 ml, injected at the site of surgery.

Main outcome variables

The primary outcome measures were pain intensity at rest and during defecation, which will be scored based on VAS by a surgical resident at 6 and 12 hours and again on days 1, 2, 7, and 14 after surgery. Pain will also be assessed after the first to fifth defecation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130826014483N12**
Registration date: **2025-06-25, 1404/04/04**
Registration timing: **prospective**

Last update: **2025-06-25, 1404/04/04**
Update count: **0**

Registration date

2025-06-25, 1404/04/04

Registrant information

Name

Mina Alvandipour

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-30, 1404/04/09

Expected recruitment end date

2025-07-31, 1404/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrasphincteric botox injection during hemorrhoidopexy with stapler on postoperative clinical outcomes of a double-blind clinical trial study

Public title

The effect of intrasphincteric botox injection during hemorrhoidopexy with stapler on postoperative clinical outcomes of a double-blind clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age Patients with symptomatic grade 3 or 4 hemorrhoids who are indicated for hemorrhoidectomy

Exclusion criteria:

Patients with inflammatory bowel disease Patients with fistula disease, Previous history of surgery in the anal area Patients with dermatitis, proctitis Patients with pregnancy-related illness Cardiovascular diseases Patients with severe respiratory illness Patients with cleft palate

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the samples, we use a block method with six blocks. In this way, from the following blocks, one is first selected at random (for example, with a dice) and according to that order, we assign the samples to 2 groups. (For example, A for the Botox group and B for the placebo group) For example, if block three is selected, the first and second samples will be assigned to group B and the third and fourth samples to group A. And we make the assignment according to that and this process will continue until the end of the sampling. If a 35-year-old woman with a body mass index of 29 is in group A, there will be other patients with similar characteristics in the control group and no cut-off is defined for these values and an attempt will be made to ensure that the patients in the two groups are similar with a reasonable and appropriate standard deviation in these variables.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the type of study design, patients and the study's conducting physicians were unaware of the intervention performed on the patients (Botox or placebo), and only the primary study analysts would be aware of the grouping of participants in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran

Street address

Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Approval date

2025-04-13, 1404/01/24

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1404.019

Health conditions studied

1

Description of health condition studied

Hemorrhoidopexy

ICD-10 code

K64.2

ICD-10 code description

Third degree hemorrhoids

Primary outcomes

1

Description

Pain intensity

Timepoint

It will be coded at 6 and 12 hours after surgery and again on days 1, 2, 7, and 14 after surgery. Pain will also be

assessed after the first to fifth bowel movements.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Wound healing quality

Timepoint

After surgery, five check-ups will be performed every two weeks from day 30 to 4 months after surgery.

Method of measurement

Information collection form

Intervention groups

1

Description

Intervention group: Botox solution manufactured by Masoon Darou Company from Iran in an amount of 0.4 ml as an injection at the site of the operation.

Category

Treatment - Drugs

2

Description

Control group: Placebo manufactured by Masoon Darou Company from Iran in an amount of 0.4 ml as an injection at the site of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran

Full name of responsible person

Mina Alvandipour

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Sponsors / Funding sources

1

Sponsor

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Mazandaran University of Medical Sciences

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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

Specialist

Other areas of specialty/work

General Surgery

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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