Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comperative evaluation of Topical Diltiazem and Botulinum toxin injection in reducing postoperative complications following Millian-morgan Hemorrhoidectomy

Protocol summary

Study aim

Comparison of the effect of topical diltiazem and botox injection on reducing pain , incidence of headache , of fecal and gas incontenency , pruritus , rate of inability to attend work or school , use of systemic analgesic and reducing complication based on age and gender after Milligan–Morgan hemorrhoidectomy

Design

A prospective, randomized, open-label clinical trial was conducted on 66 patients. Randomization was performed using Stata software version 14.2 with the stsyntax command.

Settings and conduct

The patients will be evaluated based on three study groups in terms of pain and other complications, which have been included as secondary outcomes in the questionnaire, and will be assessed on postoperative days 1, 3, and 7 by a surgery resident.

Participants/Inclusion and exclusion criteria

All patient over 18 years of age with internal,External or mixed hemorrhoids of grade 3 or 4 diagnosed are candidates for Millian -Morgan hemorrhoidectomy exclude Grade I and II hemorrhoids; the presence of other perianal pathologies including fissure, fistula, and malignancy; thrombosed hemorrhoids; history of previous perianal surgery; need for concomitant sphincterotomy; history of ischemic heart disease; heart block; pregnancy; severe hypertension; orthostatic hypotension; current use of calcium channel blockers; history of allergy to botox; and poor general condition for anesthesia corresponding to class IV or V according to the American Society of Anesthesiologists (ASA) classification.

Intervention groups

One third of the patients will be randomly assigned to receive topical diltiazem, another one third will undergo local botox injection, and in the remaining one third, as the control group, vaseline will be used as a placebo.

Main outcome variables

Comparison of the effect of topical diltiazem, as a low-cost and readily available method, with the more expensive Botox injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241022063459N1**
Registration date: **2026-09-22, 1405/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-22, 1405/06/31**
Update count: **0**

Registration date

2026-09-22, 1405/06/31

Registrant information

Name

Fatemeh Kamali pour azad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-21, 1405/06/30

Expected recruitment end date

2027-10-22, 1406/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comperative evaluation of Topical Diltiazem and Botulinum toxin injection in reducing postoperative complications following Millian-morgan Hemorrhoidectomy

Public title
Comparison of Topical Diltiazem and Botox injection in reducing postoperative complication after Millian-Morgan Hemorrhoidectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patient over 18 years of age with internal,External or mixed hemorrhoids of grade 3 or 4 diagnosed according the classification of the American Society of Colon and rectal surgeons ,who are candidates for Millian -Morgan hemorrhoidectomy
Exclusion criteria:
grade 1 and 2 hemorrhoid presence of other perianal pathologies including fissure,fistula and malignancy Thrombosed hemorrhoids history of perianal surgery need for concomitant sphincterotomy history of ischemic heart disease Heart block pregnancy sever hypertension orthostatic hypotension current use of calcium channel blockers history of allergy to botox poor general condition for general anesthesia corresponding to class 4 or 5 according to American Society of Anesthesiologists (ASA) classification
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization according to individual unit.Each patient will be assigned a number and then, using Stata software version 14.2, the following syntax will be applied: Using the command: set obs n (total number of samples), we create the required number of observations in the software, and then with the syntax: gen A = _n we generate a numbering variable called “A.” Next, using the syntax: sample n (total number of samples), count we perform randomization on the created samples. Finally, the first group (the first half of the patients) will receive topical diltiazem, and the remaining half will undergo local botox injection.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran university of medical sciences
Street address
No 20 , 130 th (jafar bye)street , Rashid street , Tehranpars , Tehran
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Province
Tehran
Postal code
1651714876
Approval date
2024-10-19, 1403/07/28
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1403.099

Health conditions studied

1

Description of health condition studied
hemorrhoid grade 3 and 4 - perianal disease
ICD-10 code
K64
ICD-10 code description
Hemorrhoids and perianal venous thrombosis

Primary outcomes

1

Description
Postoperative resting pain intensity measured by the Visual Analogue Scale (VAS)
Timepoint
post operative days 1,3and 7
Method of measurement
Pain intensity was assessed by the patient on a 10-cm linear Visual Analogue Scale (VAS), where 0 represents "no pain" and 10 represents "worst possible pain

2

Description
Postoperative defecation-related pain intensity measured by the Visual Analogue Scale
Timepoint
post operative days 1,3and 7
Method of measurement
Pain intensity was assessed by the patient on a 10-cm linear Visual Analogue Scale , where 0 represents "no pain" and 10 represents "worst possible pain

Secondary outcomes

1

Description
Total dose of Non-Steroidal Anti-Inflammatory Drugs consumed postoperatively
Timepoint
during the first seven days postoperatively
Method of measurement
The total number of doses of Non-Steroidal Anti-Inflammatory Drugs consumed by the patient during the first week after surgery was recorded using a patient data collection form

2

Description
Total Morphine Equivalent Dose of opioids consumed
Timepoint
during the first seven days postoperatively
Method of measurement
Total opioid consumption was recorded and converted into the Morphine Equivalent Dose for standardization, using a standardized

3

Description
Incidence of postoperative complications including headache, bleeding, pruritus, and fecal or gas incontinence
Timepoint
during the first seven days postoperatively
Method of measurement
The occurrence of each complication was evaluated by a surgical resident and recorded as present or absent in the patient's record

4

Description
Postoperative functional outcome measured by the Wexner score
Timepoint
On postoperative day 7
Method of measurement
The Wexner scoring system was used to evaluate the level of fecal continence, assessing the frequency of accidents and the use of pads.

5

Description
Number of days absent from work or education following surgery
Timepoint
From the day of surgery until the return to regular activities
Method of measurement
The total number of days the patient was unable to return to their occupational or educational activities was recorded based on patient self-reporting.

Intervention groups

1

Description
Intervention group: Botulinum Toxin Group.Patients in this group received an injection of Botulinum Toxin type A. The toxin was injected into the targeted muscles of the anal sphincter using a standardized dose and technique, as per the surgical protocol.
Category
Treatment - Drugs

2

Description
Intervention group: Diltiazem Group.Patients in this group were treated with Diltiazem topical gel. The gel was applied topically to the anal area according to the prescribed frequency and dosage as per the surgical protocol.
Category
Treatment - Drugs

3

Description
Control group: Vaseline Group.Patients in this group received sterile Vaseline as a placebo. It was applied topically to the anal area using the same frequency and technique as the Diltiazem gel group to maintain blinding.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Fatemeh Kamali pour azad
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Sina Hospital, Hassan Abad Square, Imam Khomeini St., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Deputy for Research and Technology, University of Tehran
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University of Tehran, 16 Azar St., Enghelab St., Enghelab Square, Tehran, Iran
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tumspr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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Fatemeh Kamali pour azad
Position
رزیدنت جراحی
Latest degree
Specialist
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data (IPD) including primary and secondary outcome measures of the study.

When the data will become available and for how long

Access will be available starting 6 months after the publication of the final results for a period of 2 years.

To whom data/document is available

Access will be available starting 6 months after the publication of the final results for a period of 2 years.

Under which criteria data/document could be used

For conducting meta-analyses or verifying study findings, provided that a validated scientific proposal is submitted and data confidentiality is maintained.

From where data/document is obtainable

Corresponding Author (Fatemeh Kamalipor azad) via Email: (f.kamalipor@gmail.com)

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

Applicants must submit a brief proposal outlining the intended use of the data. After review and approval by the research team, the data will be shared within 2 to 4 weeks.

Comments