Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Pain Reduction After Hemorrhoidectomy With Use of Diltiazim Ointment 2%

Protocol summary

Summary

This study was a randomized, double blind, prospective, placebo-controlled trial. Patients with symptomatic third and fourth degree hemorrhoids undergoing Milligan-Morgan surgery were recruited. Patients with a history of heart disease, blood pressure, orthostatic hypertension, hemorrhoid surgery, or those who had experienced side effects of calcium channel blockers and those who were pregnant were excluded. Patients were randomized to either Diltiazem or placebo treatment group. Patients were discharged after surgery with a care package that included 2% Diltiazem or placebo ointment. Patients were asked to use the ointments (1gr, 3 times daily for 1 week). Postoperative pain was evaluated using a self-administered visual analogue scale (VAS) as primary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710281558N1**
Registration date: **2009-05-08, 1388/02/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-05-08, 1388/02/18

Registrant information

Name
Farshad Jalili
Name of organization / entity
Tehran University Of Medical Sciences
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Iran (Islamic Republic of)
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jalilish@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Sina Hospital, Tehran University of Medical Sciences

Expected recruitment start date

2007-09-27, 1386/07/05

Expected recruitment end date

2008-01-02, 1386/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Pain Reduction After Hemorrhoidectomy With Use of Diltiazim Ointment 2%

Public title

Pain Reduction after Hemorrhoidectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: grade 3 and 4 hemorrhoid Exclusion Criteria: history of heart disease, blood pressure, orthostatic hypertension, hemorrhoid surgery, side effects of calcium channel blocker drugs, pregnancy.

Age

No age limit

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran Univercity of Medical Sciences
Street address
Enghelab Street
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
724

Health conditions studied

1

Description of health condition studied
haemorrhoid
ICD-10 code
I84
ICD-10 code description
Haemorrhoids

Primary outcomes

1

Description
Pain after hemorrhoidectomy
Timepoint
Every day in a week period after surgery
Method of measurement
Visual Analogue Scale(VAS)

Secondary outcomes

1

Description
Bleeding after hemorrhoidectomy
Timepoint
Baseline and 1 week after surgery
Method of measurement
Bleeding in cc by medical history

2

Description
Analgestic usage after hemorrhoidectomy
Timepoint
Baseline and 1 week after surgery
Method of measurement
Number of pills used by the paitents

Intervention groups

1

Description
Diltiazem Ointment 2%, 1 gram, 3 times daily, for 1 week, on scar
Category
Treatment - Drugs

2

Description
Placebo,3 times daily,for 1 week,on scar
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr Farshad Jalili Shahandashti
Street address
Imam khomeini Street, Imam khomeini Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dr Farshad Jalili Shahandashti
Full name of responsible person
Dr Farshad Jalili Shahandashti
Street address
Imam khomeini Avenue,Imam khomeini Street
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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
Dr Farshad Jalili Shahandashti
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Sina Hospital
Full name of responsible person
Dr Farshad Jalili Shahandashti
Position
Resident of Surgery
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Dr Hadi Ahmadi Amoli
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Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Dr Farshad Jalili shahandahti
Position
Other areas of specialty/work
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty