

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of diltiazem gel in reducing complications and pain of anorectal surgery in patients candidates for anorectal surgery

Protocol summary

Study aim

1. Comparison of the effectiveness of diltiazem and placebo gel on pain score after anorectal surgery

Design

The clinical trial consists of two groups of intervention and control. Candidates for anorectal surgery are randomly selected by blocking method. The study is a double-blind study on 144 patients and the data were collected with SPSS22 software.

Settings and conduct

This study is a double-blind randomized clinical trial. 144 patients who are candidates for anorectal surgery in Shahid Beheshti Hospital in Qom will be randomly divided into two groups. The groups will be selected in such a way that individuals will be assigned to the groups based on block randomization. The intervention group will receive diltiazem gel immediately after the operation and then every 8 to 24 hours. The actions are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria All anorectal surgery candidates who have given informed consent and Criteria for excluding clinical trial patient dissatisfaction - pregnant women - sensitivity to diltiazem gel.

Intervention groups

The intervention group is patients who are candidates for anorectal surgery who receive postoperative diltiazem gel and these patients are randomly selected and the effect of diltiazem gel on postoperative pain and postoperative complications on them is investigated. The control group of patients are candidates for anorectal surgery who receive placebo and are compared with the intervention group in terms of postoperative pain score.

Main outcome variables

pain score after anorectal surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120118008769N5**

Registration date: **2021-11-28, 1400/09/07**

Registration timing: **retrospective**

Last update: **2021-11-28, 1400/09/07**

Update count: **0**

Registration date

2021-11-28, 1400/09/07

Registrant information

Name

Seyed Jalal Eshagh Hosseini

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25171181

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j.hosseini@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of diltiazem gel in reducing complications and pain of anorectal surgery in patients candidates for anorectal surgery

Public title

Evaluating the Efficacy of Diltiazem Gel in Reducing the Complications and Pain in Anorectal Operations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for anorectal surgery Informed consent

Exclusion criteria:

Pregnant women Sensitivity to diltiazem gel

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization The study was performed using block randomization. To do this, permutation blocks have been used. Data were analyzed with SPSS 22 software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The clinical trial is two-way blind. Participants in this trial and the main researcher They do not know the type of medicine the patient is taking (diltiazem gel, placebo).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Shahid Lavasani St.

City

Qom

Province

Ghous

Postal code

3713649373

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.MUQ.REC.1400.008

Health conditions studied

1

Description of health condition studied

Anorectal surgery

ICD-10 code

K60.5

ICD-10 code description

Anorectal fistula

Primary outcomes

1

Description

Postoperative pain score

Timepoint

Immediately after surgery then every 8 hours to 24 hours

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group receiving 2% diltiazem gel from Sobhan Pharmaceutical Company, one applicator immediately after surgery and every eight hours for the first 24 hours after anorectal surgery

Category

Treatment - Drugs

2

Description

Control group: Placebo receiving group (placebo)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Farabi Limited Surgery Center

Full name of responsible person

Seyed Jalal Eshaqh Hoseini

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Shahid Beheshti St., Ammar Yaser St.

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Qom University of Medical Science

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

IR

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Seyed Jalal eshaqh Hoseini

Position

Assistant Professor

Latest degree

Subspecialist

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