

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Diltiazem gel in comparison with Lidocaine gel on the pain parameter in rectosigmoidoscopy without sedation

Protocol summary

Study aim

The effect of Diltiazem gel in comparison with Lidocaine gel on the pain parameter in rectosigmoidoscopy without sedation

Design

In this research, 80 eligible patients needed rectosigmoidoscopy referring to Qom gastroenterology clinic were chosen. Then, patients by block randomization were randomly divided into two control and intervention groups.

Settings and conduct

The study was performed as a randomized clinical trial at Shahid Beheshti Hospital in Qom. The study is double-blinded, and intervention is conducted by someone other than the care provider, and care provider and participants is unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

People entering the study aged 18 to 40 years and patients who have need general anesthesia were not included in the study

Intervention groups

Intervention group will receive the Diltiazem gel, 2cc, once, 5 minutes before rectosigmoidoscopy, rectal injection and control group will receive Lidocaine gel, 2cc, once, 5 minutes before rectosigmoidoscopy, rectal injection

Main outcome variables

Pain scale during rectosigmoidoscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161205031252N6**

Registration date: **2018-05-26, 1397/03/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-26, 1397/03/05**

Update count: **0**

Registration date

2018-05-26, 1397/03/05

Registrant information

Name

Ahmad Hormati

Name of organization / entity

Qom university of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Diltiazem gel in comparison with Lidocaine gel on the pain parameter in rectosigmoidoscopy without sedation

Public title

The effect of Diltiazem gel and Lidocaine gel on the pain of rectosigmoidoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 40 years Need to rectosigmoidoscopy Would like to participate in the study

Exclusion criteria:

Anal fissure Need general anesthesia

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization at the level of the individual

Blinding (investigator's opinion)

Double blinded

Blinding description

participants and the therapist does not know the allocation of people, and only the person who supplies the medication to the patients is aware of the type of allocation

Placebo

Not 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

No. 83, 4th alley, 1.1 alley, Safashahr Blvd

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3716987366

Approval date

2018-05-01, 1397/02/11

Ethics committee reference number

IR.MUQ.REC.1397.011

Health conditions studied

1

Description of health condition studied

Gastrointestinal bleeding

ICD-10 code

K92.2

ICD-10 code description

Gastrointestinal hemorrhage, unspecified

Primary outcomes

1

Description

Pain scale

Timepoint

During rectosigmoidoscopy

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Diltiazem gel, 2cc, once, 5 minutes before rectosigmoidoscopy, rectal injection

Category

Treatment - Drugs

2

Description

Control group: Lidocaine gel, 2cc, once, 5 minutes before rectosigmoidoscopy, rectal injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hosbital

Full name of responsible person

Ahmad Hormati

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Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Ghoum 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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Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data are specific to this study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available