

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Diltiazem Gel Versus Diltiazem Ointment in Alleviating the Symptoms of Chronic Anal Fissure; a Randomized Clinical Trial.

Protocol summary

Study aim

Evaluation of the effectiveness of diltiazem 2% topical gel and ointment in patients with chronic anal fissure.

Design

A randomized clinical trial, in two parallel-group without control, phase 3, on 70 patients. Randomization is carried out using the rand function of Excel software.

Settings and conduct

This study is carried out in a university-affiliated hospital in Tehran. Patients over 18-year-old with chronic anal fissure will be included. The research team is comprised of two surgeons and two nurses. Once the informed consent is acquired patients will be randomized into two groups 2% Diltiazem Gel or Ointment. After four weeks patients will be re-examined. Changes in the amount of pain will be evaluated using the visual analog scale and patients will be inquired about the occurrence of itching, bleeding, and any drug-related side effects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age over 18 years. 2. Symptoms of anal fissure (pain, bleeding, burning, or itching) in the last six weeks. 3. Finding one of the following signs on examination: visible sphincter fibers at the fissure base, anal papillae, sentinel piles, and indurated margins. Exclusion Criteria: 1. Past history of anal surgery 2. Current consumption of other topical or oral medication for anal fissure. 3. History of allergic reactions to diltiazem. 4. History of cardiovascular problems 5. Hypotension (systolic blood pressure < 90 mmHg). 6. History of chronic liver failure. 7. Current consumption of antihypertensive drugs. 8. Pregnancy and breastfeeding.

Intervention groups

Group A: topical treatment with diltiazem-gel 2%, two times a day q 12 hours for two months. Group B: topical treatment with diltiazem-ointment 2%, two times a day q 12 hours for two months.

Main outcome variables

Pain intensity; Age; Gender; Presence or absence of itching, bleeding, or drug-related side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141116019971N5**

Registration date: **2021-02-07, 1399/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-07, 1399/11/19**

Update count: **0**

Registration date

2021-02-07, 1399/11/19

Registrant information

Name

Ehsan Karimi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 3600

Email address

e-karimi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Diltiazem Gel Versus Diltiazem Ointment in Alleviating the Symptoms of Chronic Anal Fissure; a Randomized Clinical Trial.

Public title

Diltiazem Gel or Ointment, Which One is a Better Choice for Anal Fissure?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symptoms of anal fissure (pain, bleeding, burning, or itching) in the last six weeks. Finding one of the following signs on examination: visible sphincter fibers at the fissure base, anal papillae, sentinel piles, and indurated margins.

Exclusion criteria:

Past history of anal surgery Current consumption of other topical or oral medication for anal fissure. History of allergic reaction to diltiazem. History of cardiovascular problems including sick sinus syndrome, heart block, arrhythmia, bradycardia, heart failure, and cardiomyopathy. Hypotension (systolic blood pressure < 90 mmHg). History of chronic liver failure. Current consumption of antihypertensive drugs. Pregnancy and breast feeding. Failure to obtain informed consent.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Computer-generated block randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poorsina Avenue, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1417653861

Approval date

2020-08-15, 1399/05/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.484

Health conditions studied

1

Description of health condition studied

Anal fissure

ICD-10 code

K60.2

ICD-10 code description

Anal fissure

Primary outcomes

1

Description

Pain intensity

Timepoint

Before treatment and four weeks treatment.

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Itching

Timepoint

Before treatment and four weeks treatment.

Method of measurement

Inquiring the patient about presence or absence of itching.

2

Description

Bleeding

Timepoint

Before treatment and four weeks treatment.

Method of measurement

Inquiring the patient about presence or absence of bleeding.

3

Description

Side effects including hives, hypotension, vertigo, palpitation, light headedness.

Timepoint

Four weeks post-treatment.

Method of measurement

Inquiring the patient about presence or absence of side effects.

Intervention groups

1

Description

Intervention group: The first group will receive topical gel diltiazem 2% produced by Sobhan daroo co. two times per day q 12 hours.

Category

Treatment - Drugs

2

Description

Control group: The second group will receive topical ointment diltiazem 2% produced by Woodland hills pharmacy two times per day q 12 h.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Fospital

Full name of responsible person

Hossein Zabihi

Street address

Imam Khomeini Avenue, Hasanabad Square, Sina Hospital

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

hzabihim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Vice chancellery for research and technology, 6Th Floor, Central office of Tehran University of Medical Sciences, Qods Ave, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8163 3685

Email

drkarimi86@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Karimialavijeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Sina Hospital, Imam Khomeini Avenue, Hasan Abad Square

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

drkarimi86@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Karimialavijeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Sina Hospital, Hasan abad Square, Imam Khomeini Avenue,

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

drkarimi86@gmail.com

1136746911

Phone

+98 21 6634 8500

Email

drkarimi86@gmail.com

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

upon completion of the study, Individual participant data (anonymous) comprising age, gender, pain intensity, and vital signs will be released.

When the data will become available and for how long

Access to the information starts in 2021.

To whom data/document is available

All researchers have the possibility to access the data regardless of the research field.

Under which criteria data/document could be used

There is no specific criteria for data access.

From where data/document is obtainable

To request data access, please contact to Dr Ehsan Karimi. E-mail: drkarimi86@gmail.com, Phone number: 00989122493628, Address: Sina hospital, Imam Khomeini Avenue.

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

Upon contact, data will be sent by email.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Karimialavijeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Sina Hospital, Hasan Abad Square, Imam Khomeini Avenue.

City

Tehran

Province

Tehran

Postal code