Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Diltiazem Gel Verus 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

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Iran (Islamic Republic of)

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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 Verus 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 jel 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
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Imam Khomeini Avenue, Hasanabad Square, Sina Hospital
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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
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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
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Person responsible for updating data

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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
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