Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Metronidazole and Diltiazem Gel in Pain Control in Chronic Anal Fissure Patients

Protocol summary

Study aim
Paying attention to the effects of Metronidazole as a new method in treating patients with anal fissure

Design
Randomised, blinded, controlled clinical trial with a parallel group design of 54 patients.Randomisation was centralised with Random allocation software

Settings and conduct
This study will be conducted in 1401 to 1402 on patients suffering from chronic fissure referred to the Gastroenterology Clinic of Taleghani Hospital (Tehran). They are randomly divided into intervention group (use of Metronidazole gel) and control group by using coin toss. Metronidazole has an identification code and is distributed in the same package as Diltiazem gel. For blinding, the participant, clinical caregiver, researcher, and outcome assessor are blinded

Participants/Inclusion and exclusion criteria
Inclusion criteria: people willing to participate in the study by obtaining written consent without age and gender restrictions, presence of chronic fissure؛
Exclusion criteria: patients with other colorectal diseases, people who are not able to regularly participate in follow-up visits, acute anal fissure

Intervention groups
Patients are randomly divided into intervention and control groups. In the intervention group,topical Metronidazole gel will be used 3 times a day for 14 days, and only topical Diltiazem will be used in the control group

Main outcome variables
Determination of pain intensity in patients with chronic anal fissure treated with Metronidazole and Diltiazem gel after 10 days; Determination of pain intensity in patients with chronic anal fissure treated with Metronidazole and Diltiazem gel after 21 days

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221102056377N1**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**
Registration date
2023-01-18, 1401/10/28

Registrant information
Name
Simin Dokht Nazari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-02-04, 1401/11/15
Expected recruitment end date
2023-03-06, 1401/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of the Effectiveness of Metronidazole and Diltiazem Gel in Pain Control in Chronic Anal Fissure Patients

Public title
"Effect of Topical Metronidazole in treatment of chronic fissure"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All individuals with anal fissures for more than 6 weeks
Exclusion criteria:
Suffering from other colorectal diseases The person is unable to participate in follow-up visits Duration of symptoms less than 6 weeks
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, people were divided into intervention and control groups by simple randomization method, using the coin tossing method. Then Random allocation software was used to create a random sequence. Coded boxes with random sequences were used for concealment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Topical Metronidazole has an identification code and is supplied in the same packaging and appearance as topical Diltiazem, which will cause blinding of the participants, researchers and outcome assessors
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Shahid Beheshti University of Medical Sciences
Street address
No. 4 , Karimi Alley., Ghafari St., South Kargar Ave
City
Tehran
Province
Tehran
Postal code
1333714641
Approval date
2022-10-23, 1401/08/01
Ethics committee reference number
IR.SBMU.MSP.REC.1401.316

Health conditions studied

1

Description of health condition studied
Chronic Anal Fissure
ICD-10 code
K60.1
ICD-10 code description
Chronic anal fissure

Primary outcomes

1

Description
Determination of pain intensity in patients with chronic anal fissure treated with Metronidazole gel and diltiazem
Timepoint
Determination of pain intensity in patients with chronic anal fissure at the beginning of the study and 10, 21, 28 days after starting Metronidazole
Method of measurement
Examination of Anus; Use of Visual Analogue Scale

2

Description
Determining the duration of pain in patients with chronic anal fissure treated with Metronidazole gel and Diltiazem
Timepoint
Determining the duration of pain in patients with chronic anal fissure at the beginning of the study and 10, 21, 28 days after starting Metronidazole
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, topical

Metronidazole 0.75% (Pars Daro Pharmaceutical Company) will be used 3 times a day for 14 days

Category

Treatment - Drugs

2

Description

Control group: In the control group, only laxatives, high-fiber diet and topical Diltiazem (Soban Daru Pharmaceutical Company) will be used

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Taleghani Hospital(Tehran)

Full name of responsible person

Simin Dokht Nazari

Street address

Shahid Arabi St., Yemen st., Shahid Chamran Highway.,Ayatollah Taleghani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Shahid Arabi St., Yemen St., Shahid Chamran Highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Amir Sadeghi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Simin Dokht Nazari

Position

Resident

Latest degree

Medical doctor

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Internal Medicine

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Web page address

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

By registering the results of the clinical trial in one of the prestigious medical journals inside or outside the country

When the data will become available and for how long

6 months after publication of results

To whom data/document is available

All researchers working in academic and scientific institutions and the industry sector

Under which criteria data/document could be used

The data obtained from the clinical trial can be used by medical students, internists, gastroenterologists, surgeons and pharmacists to help treat patients with chronic fissure

From where data/document is obtainable

Dr.Simin Dokht Nazari simindokht_nazari@sbmu.ac.ir 0098 9113461557

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

After submitting the application through one of the mentioned ways and checking the person's profile, the information will be provided to the person after a time interval of approximately one month

Comments