

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3318 6469

##### Email address

simindokht\_nazari@sbmu.ac.ir

##### 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 committee 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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1985711151

**Phone**

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taleghanihospital@sbmu.ac.ir

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<https://taleghani.sbmu.ac.ir>

**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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Mpajouhesh@sbmu.ac.ir

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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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Arabi St., Yemen St., Chamran High way., Taleghani Hospital

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Amir Sadeghi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Simin Dokht Nazari  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
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[simindokht\\_nazari@sbmu.ac.ir](mailto:simindokht_nazari@sbmu.ac.ir)  
**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](mailto: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