

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Evaluation and comparison of the effect of sildenafil topical cream 10% and diltiazem gel 2% in the treatment of anal fissure

#### Protocol summary

##### Study aim

Evaluation and comparison of the effect of topical sildenafil and diltiazem gel in the treatment of anal fissure

##### Design

The study consisted of two groups receiving sildenafil topical cream and diltiazem gel. The sample size is 50 people and each study group includes 25 people. Simple randomization method and Random.org site have been used for randomization.

##### Settings and conduct

This study will perform in Khatam Al-Anbia Clinic of Yazd University of Medical Sciences. Fifty patients with anal fissure randomly entered into one of two study groups to receive one of the drug groups (sildenafil topical cream 10% and diltiazem gel 2%). Patient evaluating outcome and clinical caregivers from The type of drug was unknown. Information about the onset of analgesic effect and maximum analgesic effect will recorded and collect after drug administration.

##### Participants/Inclusion and exclusion criteria

Age 18 to 65 years as well as pain after defecation and bleeding are the conditions for inclusion in the study. Exclusion criteria are Lack of fissure pain in an unusual position and recurrent fissure

##### Intervention groups

Intervention group: sildenafil topical cream 10% was administered intra rectally 3 times daily for one week by the patient. Made in Yazd University of Medical Sciences. Intervention group: diltiazem gel 2% was used intra rectally 3 times daily for one week by the patient. Prepared in Sobhan Pharmaceutical Company

##### Main outcome variables

onset of action and decrease pain score

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20181208041882N7**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

#### Registration date

2022-05-07, 1401/02/17

#### Registrant information

##### Name

behrooz heydari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 8699

##### Email address

b.heydari@ssu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-04-21, 1398/02/01

#### Expected recruitment end date

2022-05-20, 1401/02/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation and comparison of the effect of sildenafil topical cream 10% and diltiazem gel 2% in the treatment of anal fissure

**Public title**

Evaluation of the effect of topical sildenafil and diltiazem gel in the treatment of fissures

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 65 years Having symptoms includes pain after defecation bleeding or both

**Exclusion criteria:**

Recurrent fissure Fissures in an unusual position No pain

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, a simple random method was used. Patients were divided into two treatment groups using random numbers generated by Random.org

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, patients, clinical caregivers, and outcome evaluators were not aware of the type of medication patients received. Patients in both groups received drugs in the same package.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of yazd university of medical sciences

**Street address**

Shahid Sadoughi University of medical sciences  
Shohadaye Gomnam Blve Alem Sq

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173143

**Approval date**

2019-05-19, 1398/02/29

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1398.45

**Health conditions studied****1****Description of health condition studied**

Anal fissure

**ICD-10 code**

K60.2

**ICD-10 code description**

Anal fissure, unspecified

**Primary outcomes****1****Description**

onset of pain reduction

**Timepoint**

This variable was measured after each use of the drug by the patient.

**Method of measurement**

Based on questions from the patient

**2****Description**

Maximum relaxation time

**Timepoint**

This variable was measured after each use of the drug by the patient.

**Method of measurement**

Visual Analogue Scale

**3****Description**

Duration of treatment

**Timepoint**

After complete consumption of the drug by the patient and complete recovery

**Method of measurement**

Based on questions from the patient

**4****Description**

The length of the recovery period

**Timepoint**

After taking the drug by the patient and that the patient notices a reduction in symptoms after a few days.

**Method of measurement**

Based on questions from the patient

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: : Sildenafil topical cream receives 10% 3 times a day for a week intra-anal patient Made in Yazd University of Medical Sciences

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Intervention group: The patient received diltiazem gel 2% 3 times a day for one week intra rectally.Made in Sobhan Pharmaceutical Company

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatamolambia clinic; Shahid Sadoughi hospital

##### Full name of responsible person

Mahmood Baghbaninan

##### Street address

Shahid Sadoughi hospital, Ebnesina Blvd, Shahid Ghandi Blvd

##### City

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##### Postal code

8915173149

##### Phone

+98 35 3820 8699

##### Email

b.heydari@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaei

##### Street address

Shahid Sadoughi University of medical sciences  
Shohadaye Gomnan Blvd Alem Sq

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

b.heydari@ssu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Yazd 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

Yazd University of Medical Sciences

##### Full name of responsible person

Behrooz Heydari

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

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##### Province

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Behrooz Heydari

##### Position

Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Behrooz Heydari  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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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

After nonrecognition all data can be share

### When the data will become available and for how long

6 months after publication

### To whom data/document is available

All of researchers

### Under which criteria data/document could be used

Nothing

### From where data/document is obtainable

Dr.Behrooz Heydari e.mail:b.heydari@ssu.ac.ir

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

Request your information e.mail: The data will be sent after a week

### Comments