

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison the effects of 0.5% captopril cream with 2% diltiazem cream on chronic anal fissure

#### Protocol summary

##### Summary

Anal fissure is a common disease which manifest by pain and rectal bleeding associated with bowel movement . The aim of the present study is to Comparison the effects of 0.5% captopril cream with 2% diltiazem cream in reduction of pain after defecation .Type of study:A prospective, double-blind, randomized,without placebo controled trial . inclusion criteria :Patients who had chronic anal fissure between 18-65 years old . Exclusion criteria:Individuals who show hyper sensivity to the product and the patients with hypertension using ACEI and those with increased ulcer size after using the product . intervention 1 : 0.5 % captopril cream twice daily for 2 months . intervention 2 : 2 % diltiazem cream twice daily for 2 months . outcomes : (1) pain. methods of measurement: visual analogue Scale , 2 - itching Method D-5

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201308043014N7**  
Registration date: **2014-10-12, 1393/07/20**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-10-12, 1393/07/20

##### Registrant information

##### Name

Shahram Ala

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2014-03-01, 1392/12/10

##### Expected recruitment end date

2014-09-19, 1393/06/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effects of 0.5% captopril cream with 2% diltiazem cream on chronic anal fissure

##### Public title

Effects of 0.5% captopril cream with 2% diltiazem cream on chronic anal fissure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients who had anal fissure ; between 18-65 years old exclusion criteria :Individuals who show hypersensitivity to the product ; the patients with hypertension using ACEI ; and those with increased ulcer size after using the product

##### Age

From **15 years** old to **65 years** old

##### Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mazandaran University of Medical Sciences, Ethical Committee

##### Street address

Vice chancellor of research , Moalem square

##### City

Sari

##### Postal code

#### Approval date

2013-12-22, 1392/10/01

#### Ethics committee reference number

2154

## Health conditions studied

### 1

#### Description of health condition studied

Anal fissure

#### ICD-10 code

K60.1

#### ICD-10 code description

Chronic anal fissure

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Each weeks for 2 weeks then each month for 2 month

#### Method of measurement

Visual analog

## Secondary outcomes

### 1

#### Description

itching

#### Timepoint

Each month till 2 month

#### Method of measurement

5D

## Intervention groups

### 1

#### Description

Captopril 2% cream ,BID FOR 2 Weeks for 1 cm

#### Category

Treatment - Drugs

### 2

#### Description

intervention 1 : Cream 0.5 % captopril BID for 2weeks.each dose 1 cm

#### Category

Treatment - Drugs

### 3

#### Description

intervention 2 : Diltiazem 2 % cream BID for 2 weeks each dose 1 cm

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tooba special clinic

##### Full name of responsible person

Roja Qobadi Ghadikolaei

##### Street address

Tooba special clinic, Khazar street, Sari, Iran

##### City

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences, Vice chancellor for research

##### Full name of responsible person

Doctor Ahmad Enayati

##### Street address

Mazandaran University of Medical Sciences, Vice

chancellor for research and technology, Moallem square, Sari, Mazandaran, Iran

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran University of Medical Sciences, Vice chancellor for research

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences, Vice chancellor for research

**Full name of responsible person**

Roja Qobadi Ghadikolaei

**Position**

Pharmacy student

**Other areas of specialty/work****Street address**

Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, Sari, Mazandaran, Iran

**City**

Sari

**Postal code****Phone**

+98 15 1311 0267

**Fax****Email**

roja.ghobadi@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Clinical pharmacy specialist, Faculty of pharmacy, Sari

**Full name of responsible person**

Dr Shahram Ala

**Position**

Associated professor of clinical pharmacy

**Other areas of specialty/work****Street address**

Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, Sari, Mazandaran, Iran

**City**

Sari

**Postal code****Phone**

+98 15 1354 3083

**Fax****Email**

sh204ala@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran university of medical science

**Full name of responsible person**

Dr Shahram Ala

**Position**

Associated professor of clinical pharmacy

**Other areas of specialty/work****Street address**

Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, Sari, Mazandaran, Iran

**City**

Sari

**Postal code****Phone**

+98 15 1354 3083

**Fax****Email**

sh204ala@yahoo.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*