

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Randomized double blind controlled clinical trial of Topical 0.5% minoxidil vs. 2% Diltiazem on chronic anal fissure

#### Protocol summary

##### Summary

The aim of this double blind clinical trial study is to compare the effect of 0.5% Minoxidil cream with 2% Diltiazem cream on the patients suffering from chronic anal fissure coming to Imam khomeyni hospital, in Sari, in 1393. Patients suffering from Diabetes, Hypertension, cardiovascular disease and also those consuming Anti hypertensive drugs will be excluded. The total sample which includes 110 patients, will be divided into two groups based on random-number table. The sampling will be undertaken over eight weeks. Each patient will be apply either Cream A OR B twice a day for two weeks. All of them will be refer to the Office or Surgical clinic after one and also two months afterwards. Then they will be examine by the medical team for evaluating of Wound Healing, Bleeding, Pain, Itching and Dizziness. afterwards, the collected data including the effects of the two drugs on considered Variables will be located in corresponding columns to be compared later on.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015041414483N6**

Registration date: **2015-05-12, 1394/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-12, 1394/02/22

##### Registrant information

###### Name

Mina Alvandipour

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1225 6329

###### Email address

malvandipour@mazums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Mazandaran University of Medical Sciences

###### Expected recruitment start date

2014-12-06, 1393/09/15

###### Expected recruitment end date

2015-04-20, 1394/01/31

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Randomized double blind controlled clinical trial of Topical 0.5% minoxidil vs. 2% Diltiazem on chronic anal fissure

###### Public title

The Effect of Minoxidil cream on Anal fissure

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: All the patients that are of 15 to 65 years old who had suffered from anal fissure and were not recovered after 6 weeks. Exclusion criteria: Hypertensive patients; diabetics; vascular disease and heart failures; malignant patients; the patients with history of chemotherapy; the patients who taking ACEI or Diltiazem as a medication.

###### Age

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **110**

**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

**Street address**

Moallem Sq: Sari

**City**

Sari

**Postal code**

**Approval date**

2015-03-04, 1393/12/13

**Ethics committee reference number**

13/12/1393

**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**

Anal Bleeding

**Timepoint**

Before intervention- 1,2 mo After intervention

**Method of measurement**

History

2

**Description**

Wound Healing

**Timepoint**

Before intervention- 1,2 mo After intervention

**Method of measurement**

Mucosal wound coverage

3

**Description**

Anal pain

**Timepoint**

Before intervention-1,2mo After intervention

**Method of measurement**

VAS

**Secondary outcomes**

1

**Description**

itching

**Timepoint**

Before intervention-1,2mo After intervention

**Method of measurement**

5-D pruritis scale

2

**Description**

Headache

**Timepoint**

Before intervention-1,2 mo After intervention

**Method of measurement**

VAS

3

**Description**

Decrease in BP

**Timepoint**

Before intervention-1,2 mo After intervention

**Method of measurement**

mm Hg

4

**Description**

Dizziness

**Timepoint**

Before intervention-1,2 mo After intervention

**Method of measurement**

History

5

**Description**

Allergy

**Timepoint**

Befor intervention-1,2 mo After intervention

**Method of measurement**

History

**Intervention groups****1****Description**

Group 1:patients will be apply topical 2% Diltiazem cream twice a day for two weeks.

**Category**

Treatment - Drugs

**2****Description**

Group 2: patients will be apply 0.5% Minoxidil cream twice a day for two weeks.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam khomeyni hospital

**Full name of responsible person**

Dr.Mina Alvandipour

**Street address**

Amirmazandarani St, Sari

**City**

Sari

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr.Ahmadali Enayati

**Street address**

Moallem Sq, Sari

**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

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr.Mina Alvandipour

**Position**

staff colorectal surgeon

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

Imam Khomeyni Hospital, Sari

**City**

Sari

**Postal code****Phone**

+98 11 3336 1700

**Fax****Email**

malvandipour@mazums.ac.ir

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr.Mehdi Khalvati

**Position**

Resident of surgery/student

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

Imam Khomeyni Hospital, Amirmazandarani St, Sari

**City**

Sari

**Postal code****Phone**

+98 11 3326 3974

**Fax****Email**

khalvati\_mehdi@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*