Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 compaire 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,in1393.patients suffering from Diabetes ,Hypertentsion ,cardiovascular disease and also those consuming Anti hypertensive drugs will be excluded .The total sample which includes110 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 reffer 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 patiens that are of 15 to 65 years old who had suffered from anal fissure and werent recovered after 6 weeks. Exclusion criteria: Hypertensive patients; diabeties; vascular disease and heart failures; malignant patients; the patients with history of chemoterapy; 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
Befor intervention- 1,2 mo After intervention

Method of measurement
History

2

Description
Wound Healing

Timepoint
Befor intervention- 1,2 mo After intervention

Method of measurement
Mucosal wound coverage

3

Description
Anal pain

Timepoint
Befor intervention-1,2mo After intervention

Method of measurement
VAS

Secondary outcomes

1

Description
Iitching

Timepoint
Befor intervention-1,2mo After intervention

Method of measurement
5-D pruritis scale

2

Description
Headache

Timepoint
Befor intervention-1,2 mo After intervention

Method of measurement
VAS

3

Description
Decrease in BP

Timepoint
Befor itervention-1,2 mo After intervention

Method of measurement
mm Hg

4

Description
Dizziness

Timepoint
Befor 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