Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 hypersensivity 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 Commitee
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
Iitching
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 sience

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