Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of the effectiveness topical diltiazem and nefidipin in improving symptom and healing in patient with acute fissure

Protocol summary

Study aim

Comparison of the effectiveness topical diltiazem and nefidipin in improving symptom and healing in patient with acute fissure

Design

This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of70 people in each group

Settings and conduct

The study will be conducted at Ziaeian Hospital on patients with acute fissure . Patients who signed informed consent will be randomly divided into two groups. The first group will received 0.3% nifedipine ointment (Synthesized in the pharmacy of Razi Hospital affiliated to Tehran University of Medical Sciences),Peri-anally , three times a day, quantity of a knuckle for 2 months. The Group-B will treated by 2% diltiazem ointment (Sobhan Company) Peri-anally , three times a day, amount of a knuckle for 2 months .The final outcome of the study will be assessed by a third party who is unaware of the study process. Also, the statistician will be unaware of the study process

Participants/Inclusion and exclusion criteria

Conditions for entry over the age of 18, Acute fissure, exclusion criteria history of anal surgery, Anorectal malformation and pregnancy

Intervention groups

Group-A will received 0.3% nifedipine ointment, Synthesized in the pharmacy of Razi Hospital affiliated to Tehran University of Medical Sciences, Peri-anally , three times a day, quantity of a knuckle for 2 months Group-B will treated by 2% diltiazem ointment (Sobhan Company) Peri-anally , three times a day, amount of a knuckle for 2 months

Main outcome variables

Duration of pain, healing and relapse of fissure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190414043275N1**
Registration date: **2021-07-05, 1400/04/14**
Registration timing: **prospective**

Last update: **2021-07-05, 1400/04/14**
Update count: **0**

Registration date

2021-07-05, 1400/04/14

Registrant information

Name

Zahra Momayez sanat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 9645

Email address

z-msanat@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-22, 1400/04/31

Expected recruitment end date

2021-12-20, 1400/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness topical diltiazem and nefidipin in improving symptom and healing in patient with acute fissure

Public title
Diltiazem in fissure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Acute fissure
Exclusion criteria:
Pregnancy history of anal surgery Anorectal malformation
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked

- Investigator

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization approach will be implemented in this study. Randomization will be performed using a computer-generated list. For this purpose, 140 sealed envelopes will be numbered 1-140 according to the randomization list. Group allocation will be kept separate until the study is completed. The randomization ratio would be 1: 1, with 70 envelopes allocated to each group
Blinding (investigator's opinion)
Single blinded
Blinding description
Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind. Due to the type of intervention, participants are aware of the type of treatment
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tehran university of medical science
Street address
jalal al ahmad shariati hospital
City
Tehran
Province
Tehran
Postal code
1411713135
Approval date
2020-09-07, 1399/06/17
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.420

Health conditions studied

1

Description of health condition studied
Acute anal fissure
ICD-10 code
K60.0
ICD-10 code description
Acute anal fissure

Primary outcomes

1

Description
Duration of pain
Timepoint
Before the intervention, every week for up to 8 weeks after the intervention
Method of measurement
Question from the patient

Secondary outcomes

1

Description
healing of anal fissure
Timepoint
After two months of intervention
Method of measurement
Physical examination

2

Description
Relapse
Timepoint
6 months after intervention
Method of measurement
Question from the patient

Intervention groups

1

Description
Group-A will received 0.3% nifedipine ointment, Synthesized in the pharmacy of Razi Hospital affiliated to

Tehran University of Medical Sciences, Peri-anally , three times a day, quantity of a knuckle for 2 months

Category

Treatment - Drugs

2

Description

Group-B will treated by 2% diltiazem ointment (Sobhan Company) , Peri-anally , three times a day, amount of a knuckle for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

zieaan

Full name of responsible person

zahra momayez sanat

Street address

jalal ale ahmad shariati hospital

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Tehran

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+98 21 84901

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msanat67@ gmail .com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

private

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

zahra momayez sanat

Position

associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

associated professore

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact
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Tehran University of Medical Sciences
Full name of responsible person
zahra momayez sanat
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Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available