Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation and comparison of the effect of sildenafil topical cream 10% and diltiazem gel 2%in the treatment of anal fissure

Protocol summary

Study aim
Evaluation and comparison of the effect of topical sildenafil and diltiazem gel in the treatment of anal fissure

Design
The study consisted of two groups receiving sildenafil topical cream and diltiazem gel. The sample size is 50 people and each study group includes 25 people. Simple randomization method and Random.org site have been used for randomization.

Settings and conduct
This study will perform in Khatam Al-Anbia Clinic of Yazd University of Medical Sciences. Fifty patients with anal fissure randomly entered into one of two study groups to receive one of the drug groups (sildenafil topical cream 10% and diltiazem gel 2%). Patient evaluating outcome and clinical caregivers from The type of drug was unknown. Information about the onset of analgesic effect and maximum analgesic effect will recorded and collect after drug administration.

Participants/Inclusion and exclusion criteria
Age 18 to 65 years as well as pain after defecation and bleeding are the conditions for inclusion in the study. Exclusion criteria are Lack of fissure pain in an unusual position and recurrent fissure

Intervention groups
Intervention group: sildenafil topical cream 10% was administered intra rectally 3 times daily for one week by the patient.Made in Yazd University of Medical Sciences. Intervention group: diltiazem gel 2% was used intra rectally 3 times daily for one week by the patient.Prepared in Sobhan Pharmaceutical Company

Main outcome variables
onset of action and decrease pain score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181208041882N7**
Registration date: **2022-05-07, 1401/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-07, 1401/02/17**
Update count: **0**

Registration date
2022-05-07, 1401/02/17

Registrant information

Name
behrooz heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 8699

Email address
b.heydari@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of the effect of sildenafil topical cream 10% and diltiazem gel 2%in the treatment of anal fissure

Public title
Evaluation of the effect of topical sildenafil and diltiazem gel in the treatment of fissures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years Having symptoms includes pain after defecation bleeding or both
Exclusion criteria:
Recurrent fissure Fissures in an unusual position No pain
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple random method was used.Patients were divided into two treatment groups using random numbers generated by Random.org
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, patients, clinical caregivers, and outcome evaluators were not aware of the type of medication patients received.Patients in both groups received drugs in the same package.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of yazd university of medical sciences
Street address
Shahid Sadoughi University of medical sciences Shohadaye Gomnam Blve Alem Sq
City
Yazd
Province
Yazd
Postal code
8915173143
Approval date
2019-05-19, 1398/02/29
Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.45

Health conditions studied

1

Description of health condition studied
Anal fissure
ICD-10 code
K60.2
ICD-10 code description
Anal fissure, unspecified

Primary outcomes

1

Description
onset of pain reduction
Timepoint
This variable was measured after each use of the drug by the patient.
Method of measurement
Based on questions from the patient

2

Description
Maximum relaxation time
Timepoint
This variable was measured after each use of the drug by the patient.
Method of measurement
Visual Analogue Scale

3

Description
Duration of treatment
Timepoint
After complete consumption of the drug by the patient and complete recovery
Method of measurement
Based on questions from the patient

4

Description
The length of the recovery period
Timepoint
After taking the drug by the patient and that the patient notices a reduction in symptoms after a few days.
Method of measurement
Based on questions from the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: : Sildenafil topical cream receives 10% 3 times a day for a week intra-anal patient Made in Yazd University of Medical Sciences
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: The patient received diltiazem gel 2% 3 times a day for one week intra rectally.Made in Sobhan Pharmaceutical Company
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatamolanbia clinic; Shahid Sadoughi hospital
Full name of responsible person
Mahmood Baghbaninan
Street address
Shahid Sadoughi hospital, Ebnesina Blvd, Shahid Ghandi Blvd
City
Yazd
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Postal code
8915173149
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+98 35 3820 8699
Email
b.heydari@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Shahid Sadoughi University of medical sciences Shohadaye Gomnan Blvd Alem Sq
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Postal code
8915173149
Phone
+98 35 3820 3410
Email
b.heydari@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Behrooz Heydari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After nonrecognition all data can be share

When the data will become available and for how long

6 months after publication

To whom data/document is available

All of researchers

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

Dr.Behrooz Heydari e.mail:b.heydari@ssu.ac.ir

What processes are involved for a request to access data/document

Request your information e.mail: The data will be sent after a week

Comments