Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of combination gel (diltigel2%-ureacolchicine) with diltigel 2% in the treatment of acute anal fissures

Protocol summary

Study aim
Comparison of the effectiveness of combination gel (diltigel2% -urea-colchicine) with.diltigel2% in the treatment of acute anal fissures

Design
Clinical trial with control group, with parallel groups, single-blind, randomized, phase 0 on 80 patients. The rand function of Excel software was used for randomization

Settings and conduct
Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria
The criteria for entering the study include being over 18 years old, agreeing to participate in the study, suffering from fissure anus as diagnosed by a specialist doctor, and the exclusion criteria from the study include suffering from irritable bowel syndrome, receiving chemotherapy drugs, being under radiotherapy, History of Fisher and hemorrhoid surgery

Intervention groups
From the moment of entering the study, patients will change their lifestyle in the form of using high-fiber foods, avoiding spicy foods, and using laxatives in case of constipation.

Main outcome variables
Effectiveness of combined gel (diltigel2%, urea, colchicine) in the treatment of acute anal fissures: a randomized, single-blind clinical trial 2. Efficacy of Diltigel2% in the treatment of acute anal fissures: a single blind randomized clinical trial 3. Comparing the effectiveness of combined gel (Diltigel, Colchicine- Urea) with Diltigel gel in the treatment of acute anal fissures: a single blind randomized clinical trial

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221203056698N1**
Registration date: **2023-10-11, 1402/07/19**
Registration timing: **prospective**

Last update: **2023-10-11, 1402/07/19**
Update count: **0**

Registration date
2023-10-11, 1402/07/19

Registrant information

Name
Ramin Azhough

Name of organization / entity

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Iran (Islamic Republic of)

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+98 41 3382 1629

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azhoughrr@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-10, 1402/09/19

Expected recruitment end date
2024-03-17, 1402/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of combination gel (diltigel2%-ureacolchicine) with diltigel 2% in the treatment of acute anal fissures

Public title

Effect of new combination gel in the treatment of acute anal fissures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Consent to participate in the study Suffering from acute anal fissure as diagnosed by a specialist doctor

Exclusion criteria:

Having IBD Receiving chemotherapy drugs Being under radiotherapy History of Fisher and hemorrhoid surgery Receiving medicine and herbal gel for the treatment of fissure Receiving Diltigel before entering the study Receiving lidocaine and tetracycline before entering the study Having gout History of uncontrolled blood pressure Allergy to the drugs used in this study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients after entering the study in blocks of four in two groups will be divided. Since the primary investigator of this study is the prescribing physician, he is able to be blinded will not be in the course of study; But the person analyzing the data will be unaware of the type of patient grouping The study flow will be blind; Therefore, the present study will be a single-blind study

Blinding (investigator's opinion)

Single blinded

Blinding description

After entering the study, patients will be divided into two groups in blocks of four. Since the first conductor of this study is the prescribing physician, he will not be able to be blind during the study; However, the person analyzing the data as well as evaluating the results, who will be unaware of the type of patient grouping, will be blind during the study; Therefore, the present study will be a double-blind study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tabriz University of Medical Sciences

Street address

golgasht,Tabriz University of Medical Sciences

City

tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TBZMED.REC.1402.103

Health conditions studied

1

Description of health condition studied

Acute anal fissures

ICD-10 code

K60.2

ICD-10 code description

Anal fissure, unspecified

2

Description of health condition studied

Acute anal fissures

ICD-10 code

K60.2

ICD-10 code description

Anal fissure, unspecified

Primary outcomes

1

Description

The amount of pain in the follow-up periodPatients will be asked.

Timepoint

Patients will be checked for symptoms in the second week (face-to-face visit), the fourth week (telephone follow-up), the sixth week (telephone follow-up), the eighth week (telephone follow-up) and the twelfth week (face-to-face visit).

Method of measurement

The intensity of pain will be checked for each patient at the mentioned times and recorded in the data collection form of each person. This form contains information such as age, sex, body mass index, diabetes mellitus, education level, occupation, duration of illness and having crown skin. The intensity of pain will be checked with the help of visual pain scale (VAS).

2

Description
The amount of itching in the follow-up periodPatients will be asked

Timepoint
Patients will be checked for symptoms in the second week (face-to-face visit), the fourth week (telephone follow-up), the sixth week (telephone follow-up), the eighth week (telephone follow-up) and the twelfth week (face-to-face visit).

Method of measurement
The intensity of itching will be checked for each patient at the mentioned times and recorded in the data collection form of each person. This form contains information such as age, sex, body mass index, diabetes mellitus, education level, occupation, duration of illness and having crown skin.and all the datas will be collected by the same person

3

Description
The amount of bleeding in the follow-up periodPatients will be asked.

Timepoint
Patients will be checked for symptoms in the second week (face-to-face visit), the fourth week (telephone follow-up), the sixth week (telephone follow-up), the eighth week (telephone follow-up) and the twelfth week (face-to-face visit).

Method of measurement
The intensity of bleeding will be checked for each patient at the mentioned times and recorded in the data collection form of each person. This form contains information such as age, sex, body mass index, diabetes mellitus, education level, occupation, duration of illness and having crown skin.and all the datas will be collected by the same person

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the patients of this group, 2% Diltigel gel will be administered externally once every twelve hours.

Category
Treatment - Drugs

2

Description
Intervention group: For the patients of the other group, a gel prepared by a pharmacist in the form of a combination of 30 grams of Diltigel 2%, 67 grams of urea, and 3 grams of colchicine will be prescribed twice a day and externally.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical School of Tabriz University Of Medical sciense
Full name of responsible person
Ramin Azhugh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi (Research assistant of Tabriz University of Medical Science)
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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
Tabriz University of Medical Sciences

Proportion provided by this source
20

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

Tabriz University of Medical Sciences

Full name of responsible person

Ramin Azhugh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Latest degree

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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