

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

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 1629

Email address

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 science

Full name of responsible person

Ramin Azhugh

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3332 5360

Email

danesh@tbzmed.ac.ir

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)

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3336 5890

Email

danesh@tbzmed.ac.ir

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

+98 41 3333 5698
Email
danesh@tbzmed.ac.ir

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
General Surgery
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
+98 41 3335 6047
Email
danesh@tbzmed.ac.ir

Person responsible for scientific 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
General Surgery
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone

Person responsible for updating data

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
General Surgery
Street address
gholghasht
City
tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
0413335698
Email
danesh@tbzmed.ac.ir

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