Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of The efficacy of Anti-fissure barij cream and diltiazem gel in severity of pain, bleeding and healing of anal fissure

Protocol summary

Study aim
Comparison of the efficacy of Barriage Antifischer cream and Diltiazem gel in reducing the severity of anal fissures and their complications.

Design
Randomization will be conducted using a block method with blocks of four, considering Group A as receivers of Antifischer cream and Group B as receivers of Diltiazem gel. A total of 80 participants will be enrolled in Phases 1-2 of this trial. The study will be double-blind, and the Python randint function will be used for randomization.

Settings and conduct
The study will be conducted at the surgical clinic of Shahid Beheshti Hospital in Kashan. The trial will employ a double-blind approach, where both the clinical evaluators and the patients are blinded to the groups. This is achieved by providing the gel or cream in colorless tubes without any branding, and even the evaluators do not know which is the gel and which is the cream.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with acute fissure aged over 15 years. Exclusion criteria: Hemorrhoids, anal fistula, anal abscess, pregnancy and lactation, malignant diseases.

Intervention groups
Intervention Group A: Receivers of Barriage Antifischer cream with essence: The cream is to be applied twice daily using an applicator at the anal site. Intervention Group B: Receivers of 2% Diltiazem gel by Sobhan Darou: The gel is to be applied twice daily using an applicator at the anal site.

Main outcome variables
Fissure grade after treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210110049992N1**
Registration date: **2025-02-18, 1403/11/30**
Registration timing: **prospective**

Last update: **2025-02-18, 1403/11/30**
Update count: **0**

Registration date
2025-02-18, 1403/11/30

Registrant information
Name
Hossein Rezaei
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 5557 8010
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-09, 1403/12/19

Expected recruitment end date
2025-06-09, 1404/03/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of The efficacy of Anti-fissure barij cream and diltiazem gel in severity of pain, bleeding and healing of anal fissure

Public title
Anti-fissure cream and diltiazem gel on anal fissure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with acute fissure Age more than 15 years old
Exclusion criteria:
Hemorrhoid Anal fistula Anal abcess Pregnancy Breastfeeding Malignancy
Age
From **15 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Block Unit of randomization: Individual Randomization tool: Python software with the randint function, random sequence in blocks of four individuals, considering A as Antifischer cream and B as Diltiazem gel, with sequences such as AABB, BBAA, BABA, ABAB, BAAB, ABBA. Both Antifischer cream and Diltiazem gel are colorless and odorless. Both will be packaged in unmarked, brand-free tubes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the Antifischer cream and the Diltiazem gel are colorless and odorless. They will both be contained in tubes that lack any markings or brand identifiers. Clinical evaluators will receive these tubes and administer them to patients according to specified guidelines, while only the researchers are aware of the type of these tubes. Patients are also unaware whether they are receiving Diltiazem gel or Antifischer cream.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Pezeshk Blvd. - Qotb Blvd.
City
Kashan
Province
Isfehan
Postal code
8715981151
Approval date
2022-02-09, 1400/11/20
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1400.196

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
Anal fissure grade after treatment
Timepoint
0, 2 weeks, 4 weeks, 6 weeks, and 8 weeks after treatment
Method of measurement
Clinical examination by a physician and decisions based on the following grades:Grade 0: HealedGrade 1: Fissure with visible internal anal sphincterGrade 2: Deeper fissures with more extensive visibility of the internal anal sphincterGrade 3: Fissure with indeterminate depthGrade 4: Accompanied by perianal fistula

Secondary outcomes

1

Description
Hemorrhage grade
Timepoint
0, 2 weeks, 4 weeks, 6 weeks, 8 weeks after treatment initiation
Method of measurement
Asking the patient: Score 0: No bleedingScore I (mild): Presence of blood streaks in stoolScore II (moderate): Intermittent bleeding during defecationScore III (severe): Continuous bleeding during defecation

2

Description
Pain severity during defication
Timepoint

0, 2 weeks, 4 weeks, 6 weeks, 8 weeks after treatment initiation

Method of measurement

Pain Severity: Numeric Rating Scale (NRS-11) - This is a patient-reported scale used for adults and children aged 10 years or older. It is defined as follows:Score 0: No painScore 1-3: Mild pain (annoying but causes little interference with daily activities)Score 4-6: Moderate pain (significantly interferes with daily activities)Score 7-10: Severe pain (disabling and unable to perform daily activities)

Intervention groups

1

Description

Intervention Group A: Receives Barriage Essence company's Antifischer cream, applied twice daily using an applicator at the anal site. The cream will be provided in 50-gram tubes, uniform in color and size, and filled in the formulation section of Barriage Essence pharmaceutical company.

Category

Treatment - Drugs

2

Description

Intervention Group B: Receives 2% Diltiazem gel from Sobhan Darou company. Applied twice daily using an applicator at the anal site. The gel will be provided in 50-gram tubes, uniform in color and size, and filled in the formulation section of Barriage Essence pharmaceutical company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Surgical Clinic of Shahid Beheshti Hospital in Kashan.
Full name of responsible person
Abdolhosein Davoodabadi
Street address
Pezeshk Blvd. - Qotb Blvd.
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8715981151
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Davoodabadi-A@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
barijessence company
Full name of responsible person
Abdolhosein Davoodabadi
Street address
Pezeshk Blvd. - Qotb Blvd.
City
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+98 31 5547 2939
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

barijessence company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Abdolhosein Davoodabadi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Abdolhosein Davoodabadi

Position

Professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All information related to the participants will be accessible alongside the study protocol.

When the data will become available and for how long

The access period will begin 6 months after the publication of the results.

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

Only academic researchers will have access by submitting a request to the corresponding author.

From where data/document is obtainable

By sending an email to the corresponding author of the paper.

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

Emails sent to the corresponding author will be reviewed within 3 weeks, and responses will be sent to the individual via email.

Comments