Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness, recurrence rate and side effects of two therapeutic methods of Botulinum toxin injection and topical Diltiazem in the treatment of patients with chronic anal fissures

Protocol summary

Study aim

Determining and comparing the clinical effectiveness, recurrence and side effects of two therapeutic methods of botulinum toxin injection and local diltiazem in the treatment of chronic anal fissure.

Design

Clinical trial with two intervention groups with accessible sampling method, phase 2 on 60 patients.

Settings and conduct

With the available sampling method, a number of patients with chronic anal fissure who refer to the surgery clinic of Gonabad city are selected. After receiving the necessary information about how to perform both treatment methods, patients consciously choose a group. Finally, using the relevant checklists that are completed by the patient and the specialist doctor, the treatment results and side effects of the two methods are checked and compared.

Participants/Inclusion and exclusion criteria

Age between 18 and 80 years, no immune deficiency, no inflammatory bowel diseases and no tuberculosis, no recurrent anal fissure and complex anal fissure, no colon malignancy, no pregnancy, no reaction and allergy to medicinal substances

Intervention groups

In the diltiazem (A) group, 2% diltiazem ointment is prescribed locally around the anus three times a day (every 8 hours) for one week. In the toxin group (B), 100 units of Botox are injected in four divided doses of 25 units at 3, 6, 9, and 12 hours in the internal anal sphincter.

Main outcome variables

Clinical efficacy and disease recovery; Rate of disease recurrence; The amount of side effects; Duration of response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230607058408N1**
Registration date: **2023-06-29, 1402/04/08**
Registration timing: **prospective**

Last update: **2023-06-29, 1402/04/08**
Update count: **0**

Registration date

2023-06-29, 1402/04/08

Registrant information

Name

Fahime Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5725 0779

Email address

fahimemehrabi99@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness, recurrence rate and side effects of two therapeutic methods of Botulinum toxin injection and topical Diltiazem in the treatment of patients with chronic anal fissures

Public title
Investigating the effect of topical diltiazem and botulinum toxin injection in the treatment of chronic anal fissure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People with chronic anal fissure between the ages of 18 and 80

Exclusion criteria:
Immune deficiency (using corticosteroids for more than 3 months, patients receiving transplants, receiving chemotherapy or radiotherapy, HIV positive patients with CD4 less than 200) Inflammatory bowel diseases Tuberculosis Recurrent anal fissure and complicated anal fissure (stenosis, abscess, fistula or hemorrhoids) Colon malignancy Pregnancy

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
How to assign people to two intervention groups: with the available sampling method, a number of patients with chronic anal fissure referring to the surgery clinic are selected and after receiving the necessary information about how to perform both treatment, They consciously choose a group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of gonabad university of mwdical sciences

Street address
Gonabad university of medical sciences , DR Mahdizade Blvd

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2023-02-21, 1401/12/02

Ethics committee reference number
IR.GMU.REC.1401.173

Health conditions studied

1

Description of health condition studied
Chronic anal fissure

ICD-10 code
K60.1

ICD-10 code description
Chronic anal fissure

Primary outcomes

1

Description
Chronic anal fissure

Timepoint
Examination of anal fissure at the beginning of the study and 14 days later and at the end of the first, second, fourth and sixth months after the intervention

Method of measurement
Checklist and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group one: Injection of 100 units of Botox in four divided doses of 25 units at 3, 6, 9 and 12 hours in the internal anal sphincter

Category
Treatment - Drugs

2

Description
Intervention group two: Administration of 2% diltiazem ointment topically around the anus three times a day (every 8 hours) for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Allameh Bahloul Gonabad Hospital
Full name of responsible person
Fahime Mehrabi
Street address
Gonabad university of medical sciences , DR Mahdizade Blvd
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Fahimemehrabi99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr Leila Sadeq moghadam
Street address
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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
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Fahime Mehrabi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

Contact

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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