

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 medical 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bahloul Gonabad Hospital

Full name of responsible person

Fahime Mehrabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Leila Sadeq moghadam

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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

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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