

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Botox and Botox in addition to Diltiazem ointment for the treatment of chronic anal fissure

Protocol summary

Study aim

Evaluation of the effect of "Botox in addition to diltiazem ointment" in the treatment of chronic anal fissure

Design

A prospective randomized controlled clinical trial, phase 3, is conducted on 64 patients with chronic anal fissure. For randomization, first 64 balls from number 1 to 64 are considered and then randomly divided into two equal parts including group 1 (intervention) and group 2 (control) and then using a lottery container, the ball of each group was taken out and the intended sequence was recorded.

Settings and conduct

Eligible patients referred to Kosar Hospital in Semnan will be examined after being assigned to the intervention or control group and receiving the intervention. Patients are visited in future at intervals of 3, 6, and 12 weeks after the intervention, and each time fissure's degree, pain score, bleeding, gas or stool incontinence will be assessed.

Participants/Inclusion and exclusion criteria

64 patients with chronic fissure with a posterior or anterior linear ulcer and a skin tag, induration of the wound edges, visible internal sphincter muscle fibers in the wound base and symptoms of pain and bleeding following defecation for at least 8 weeks were included in the study. Patients with fistula, anal abscess, symptomatic hemorrhoids, acute fissure (less than eight weeks of symptoms), irritable bowel syndrome, and a history of anal surgery, pregnancy, or breastfeeding are excluded.

Intervention groups

In both groups, patients receive 20 units of Botox. We recommend that all patients follow a high-fiber diet. In the case group, 2% diltiazem ointment is prescribed after Botox injection. In future, fissure's degree, pain score, bleeding, gas or stool incontinence will be assessed.

Main outcome variables

Degree of anal fissure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N13**

Registration date: **2021-05-25, 1400/03/04**

Registration timing: **prospective**

Last update: **2021-05-25, 1400/03/04**

Update count: **0**

Registration date

2021-05-25, 1400/03/04

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7844

Email address

mehrdadzahmatkesh@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Botox and Botox in addition to Diltiazem ointment for the treatment of chronic anal fissure

Public title

Evaluation of the effect of Botox in addition to Diltiazem ointment in chronic anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A posterior or anterior linear ulcer with a skin tag
Induration of the wound edges Visible internal sphincter muscle fibers in the base of wound Pain and bleeding following defecation for at least 8 weeks

Exclusion criteria:

Fistula Anal abscess Symptomatic hemorrhoids Acute fissure (less than eight weeks) Irritable bowel syndrome Anal surgery pregnancy or lactation.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, at first stage, 64 spheres from one to 64 are considered and following that will randomly divided into two equal parts, including "1" (Intervention) and group 2 (Control), and then using a lottery container, the ball of each group taken out and the intended sequence will be recorded.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Central office of Semnan University of Medical Sciences, Basidj Boulevard

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-02-23, 1399/12/05

Ethics committee reference number

IR.SEMUMS.REC.1399.350

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

Degree of anal fissure

Timepoint

3, 6, and 12 weeks after the intervention

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients in the intervention group, 20 units of Botox will be injected by a 25 gauge needle into the internal sphincter at three and 9 o'clock (10 units per location) while the patient is in the jack knife position. Then, Diltiazem 2% is prescribed as ointment, which should be used one centimeter, 3 times a day, into the anus area and on the fissure for 6 weeks.

Category

Treatment - Other

2

Description

Control group: For patients in the intervention group, 20 units of Botox will be injected by a 25 gauge needle into the internal sphincter at 3 and 9 o'clock (10 units per location) while the patient is in the jack knife position.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Mahdis Aghaee

Street address

Amin Avenue, Basidj Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei MD

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Researchman

Latest degree

Bachelor

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Setareh Soltany MD

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Researchman

Latest degree

Bachelor

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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

Yes - There is 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

Anonymised data will be offered.

When the data will become available and for how long

After publishing of final report

To whom data/document is available

Researcher who working in academic institutions

Under which criteria data/document could be used

Referees and competent people

From where data/document is obtainable

Contact with scientific responsible

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

After verifying the applicant's position

Comments