Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 23 3343 7844

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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
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Amin Avenue, Basidj Boulevard
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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 updating data

Contact

Name of organization / entity
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Full name of responsible person

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Position
Researchman

Latest degree
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Other areas of specialty/work
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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