Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of combined injection of platelet-enriched plasma with Botulinum toxic in pain relief and anal fissure repair : a randomized, controlled, clinical trial study

Protocol summary

Study aim

Determining the effectiveness of combined injections of platelet-rich plasma and Botox in pain and healing chronic anal fissures.

Design

A controlled, parallel-group, randomized, phase 3 clinical trial on 144 patients. Randomization will be performed using the blockrand package of R software.

Settings and conduct

This study is a randomized controlled clinical trial in which the effectiveness of platelet-rich plasma injection with botulinum toxin (intervention group) compared to Botox (control group 1) and diltiazem gel (control group 2) in improving pain and healing of chronic anal fissure in patients with chronic anal fissure referred to Shohada Ashayer Hospital in Khorramabad will be investigated.

Participants/Inclusion and exclusion criteria

People over 18 years of age with anterior and posterior anal fissures for 3 months or more and skin tags on rectal examination will be included in the study. People with anal fissures associated with other conditions, blood and psychiatric diseases, and a history of lateral sphincterotomy will be excluded from the study.

Intervention groups

This study includes intervention and control groups, in which the intervention group will receive Botox injections with platelet-rich plasma, in the first control group Botox injections, and in the second control group diltiazem gel will be used.

Main outcome variables

Symptomatic improvement of anal pain after defecation; assessment of sphincter tone; defecation straining; gas and stool incontinence; rectal bleeding; patient's overall perception of improvement; recurrence of fissures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251130068162N1**
Registration date: **2025-12-19, 1404/09/28**
Registration timing: **prospective**

Last update: **2025-12-19, 1404/09/28**
Update count: **0**

Registration date

2025-12-19, 1404/09/28

Registrant information

Name

Mohamadreza Mohades

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effectiveness of combined injection of platelet-enriched plasma with Botulinum toxic in pain relief and anal fissure repair : a randomized, controlled, clinical trial study

Public title
Investigating the effectiveness of combined injection of platelet-enriched plasma with Botulinum toxic in pain relief and anal fissure repair : a randomized, controlled, clinical trial study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals must be 18 years of age or older. must have a history of painful anal fissure (AF) for three months (90 days) or longer prior to screening No history of diabetes Presence of a radial fissure with indurated edges observed on anorectal examination Presence of either anterior or posterior anal fissure Presence of a skin tag observed during anorectal examination For individuals who have been using other topical medications, a washout period of at least two weeks prior to the start of the study will be required.

Exclusion criteria:
Individuals who are unwilling to undergo AF examination involving the anal canal or perianal region. Individuals who have undergone lateral sphincterotomy, anal dilation, or any previous interventions the anal canal or perianal region.Individuals who have used glyceryl trinitrate (GTN) ointment for more than one week during the 4 weeks prior to the screening visit, within a 6-month period. Anal fissure associated with other conditions (e.g., trauma, HIV infection, fistula, inflammatory bowel disease, perianal sepsis, or malignancy). Individuals who are expected to undergo another treatment plan requiring hospitalization during the study. History of cardiovascular disease, inflammatory bowel disease, chronic fecal incontinence, prior pelvic radiotherapy, fixed anal stenosis/fibrosis, major psychiatric disorders (including cigarette, drug, or alcohol users), or hematologic . Use of investigational drugs within 8 weeks or a period equal to five half-lives prior to screening, whichever is longer. diseases Individuals who may be unavailable during the trial period, are unlikely to comply with the protocol, or are otherwise deemed unsuitable by the physician for any reason.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are entered into the study based on inclusion and exclusion criteria as available until the sample size is completed. Then, they are assigned to study groups using the block randomization method. For each block, permutations of 3 and 6 are considered so that the prediction of the next assignment is not possible. Randomization will be done using the blockrand package of R software. To implement the random sequence on the participants in the study, sealed, opaque envelopes with a random sequence are used. A number of envelopes are prepared, and each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order. In order to maintain the random sequence, numbering is performed on the outer surface of the envelopes in the same order. Finally, the envelope flaps are glued and placed in boxes in order. At the start of participant enrollment, according to the order of entry of eligible participants into the study, one of the envelopes is opened in order, and the assigned group of that participant is revealed.

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 lorestan University of Medical Sciences

Street address
kamalvand

City
khoram abbad

Province
Lorestan

Postal code
6816887864

Approval date
2025-11-22, 1404/09/01

Ethics committee reference number
IR.LUMS.REC.1404.326

Health conditions studied

1

Description of health condition studied
anal fissure

ICD-10 code
K60.1

ICD-10 code description

Chronic anal fissure

Primary outcomes

1

Description
pain
Timepoint
0,1,6,12 weeks
Method of measurement
Improvement of post-defecation anal pain based on the Numerical Rating Scale (NRS): Changes in pain scores were measured at baseline (i.e., before the start of the study) and at 1, 6, and 12 weeks after the start of the study. Pain was assessed using the Numerical Rating Scale, ranging from 0 to 10, where 0 = no pain and 10 = worst possible pain.

Secondary outcomes

1

Description
recurrence of the anal fissure
Timepoint
It is measured at 1 week, 6 weeks, and 12 weeks from the start date of the study.
Method of measurement
Anatomical examination

Intervention groups

1

Description
Intervention group:In this group, each patient receives 0.4 ml of Botox divided into two injections of equal volume on both the right and left lateral sides of the fissure. The injection is performed with a 27-gauge needle. The solution is injected close to the fissure on the lateral side. No sedation or local anesthesia will be used. Patients in the treatment group receive 20 units of botulinum toxin A (Botox 50 units per milliliter), then local anesthesia with all aseptic measures will be performed for PRP injection (ready-made PRP kits are used in this study). Anorectal dilatation is performed in the jack-knife position. Once the anal spasm is relieved, a speculum is placed in the anal canal and the fissure is observed on the clock indicator. The PRP sample is drawn and injected into the fissure bed to the submucosal layer with an insulin needle at a 45-degree angle. We wait for complete hemostasis to be achieved. Dressing is done with all aseptic precautions.
Category
Treatment - Surgery

2

Description
Control group1: In this group, each patient receives 0.4 ml of Botox divided into two equal injections into the right and left lateral sides of the fissure. The injection is performed with a 27-gauge needle. The solution is injected close to the fissure on the lateral side. Sedation or local anesthesia will not be used. Patients in the treatment group receive 20 units of botulinum toxin A (50 units of Botox per ml).
Category
Treatment - Surgery

3

Description
Control group2: In this group, patients apply a fingertip amount of diltiazem gel around their anus every 12 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
shohadai ashayer khorram abbad hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
univercity
Proportion provided by this source
1
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
"All data can potentially be shared after the individuals are de-identified
When the data will become available and for how long
after impression
To whom data/document is available
"Researchers
Under which criteria data/document could be used
Research use
From where data/document is obtainable

mohadesreza8@gmail.com

one to six month

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

Comments