Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Partial Lateral Internal Sphincterotomy Versus Combined Botulinum Toxin A Injection and Topical Application of Diltiazem in treatment of chronic anal fissure

Protocol summary

Summary

Objectives: A randomized control trial is performed to compare efficacy and complications of combined topical diltiazem (DTZ) gel and botulinum toxin A injection (BTA) versus partial lateral internal sphincterotomy (PLIS).management of chronic anal fissure remains a challenging issue. PLIS provides high cure rate with the expense of considerable risk of incontinence. DTZ and BTA have been widely used for medical sphincterotomy. However, no study has compared the effectiveness of combined DTZ and BTA with PLIS.Setting: This study conducts at Sina hospital. Design and intervention: 99 patients will randomly assigned to receive combined topical DTZ ointment and BTA injection or partial lateral internal incterotomy (PLIS) . Participants including major eligibility criteria: Diagnosis of chronic anal fissure on physical examination (based on having indurations at the edges and having at least two criteria of these three including skin tag, hypertrophied anal papillae and exposed internal sphincter muscle fiber) by an experienced colorectal surgeon associated with painful defecation for at least 2 month. Main outcome measure variables: Efficacy and complications following each treatment will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042812294N3**
Registration date: **2013-10-21, 1392/07/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-21, 1392/07/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Partial Lateral Internal Sphincterotomy Versus Combined Botulinum Toxin A Injection and Topical Application of Diltiazem in treatment of chronic anal fissure

Public title

Partial Lateral Internal Sphincterotomy Versus Combined Botulinum Toxin A Injection and Topical Application of Diltiazem in Treatment of Chronic Anal Fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of chronic anal fissure on physical examination (based on having indurations at the edges and having at least two criteria of these three including skin tag; hypertrophied anal papillae and exposed internal sphincter muscle fiber) by an experienced colorectal surgeon associated with painful defecation for at least 2 month; age between 18 and 100 years old. Exclusion criteria: acute anal fissure (experiencing symptoms less than two months); pregnancy; secondary anal fissure; hypersensitivity to DTZ or BTA; cardiovascular disease; previous history of anal surgery; atypical fissure and chronic headache.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Sciences.

Street address

1136746911, Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

City

Tehran

Postal code

1136746911

Approval date

2012-09-16, 1391/06/26

Ethics committee reference number

911301304

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

wound healing

Timepoint

one week, 1,2,6 and 12 months postoperatively

Method of measurement

Complete Wound Healing (macroscopic epithelialization)

Secondary outcomes

1

Description

complications

Timepoint

, one week, 1,2,6,12 months postoperatively

Method of measurement

physical examination and history taking, VAS

2

Description

Induration, hypertrophied papilla, exposing internal anal sphincter,skin tag

Timepoint

before and after surgery

Method of measurement

physical examination

3

Description

pain

Timepoint

before treatment, 1 week, 1,2,6 and 12 months postoperatively

Method of measurement

visual analog scale

4

Description

chronicity of fissure

Timepoint

before treatment

Method of measurement

history taking

5

Description
fissure localization
Timepoint
before treatment
Method of measurement
physical examination

6

Description
bleeding
Timepoint
before treatment, 1 week, 1,2,6 and 12 months postoperatively
Method of measurement
history taking

7

Description
pain at night
Timepoint
before treatment, 1 week, 1,2,6 and 12 months postoperatively
Method of measurement
history taking

8

Description
recurrence
Timepoint
1 ,2,6 and 12 month postoperatively
Method of measurement
history taking and physical examination

Intervention groups

1

Description
Intervention group: Under local anesthesia (with lidocaine 5% gel) on left sided or knee elbow position. BTA is injected into the internal anal sphincter on the both sides of anterior midline in equal doses. These patients will be advised to receive 2% DTZ ointment three times daily for six weeks which applied to the perianal region and anus.
Category
Treatment - Drugs

2

Description
Control group: under spinal anesthesia in the lithotomy position; internal sphincter muscle fibers were partially cut at 3 o'clock position under direct visualization with a transverse incision up to the height of the fissure apex using a cautery. In this study, skin tags and hypertrophied anal papillae were also removed.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty