

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of lateral internal sphincterotomy and botulinum toxin injection in treatment of chronic anal fissure

Protocol summary

Summary

The aim of this study is to compare the complications and outcomes of botulinum toxin injection with partial lateral internal sphincterotomy in the treatment of chronic anal fissure. This study is a randomized controlled clinical trial, done in surgical department of Hamedan Besat hospital. All of the patients with diagnosis of chronic anal fissure and triad of sentinel pile, hypertrophy of papi, and fibrosis of bed wound consist of 86 patients are assigned to undergo partial lateral internal sphincterotomy under general anesthesia or receive an injection of 12.5 unit of toxin on both sides of anus (totally, 25 units) under local anesthesia using lidocaine gel. Improvement rate and complications including pain and bleeding will be compared in the two follow-up periods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011285263N1**

Registration date: **2011-02-03, 1389/11/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-02-03, 1389/11/14

Registrant information

Name

Hamid Reza Fereidoonian

Name of organization / entity

Hamedan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Hamedan University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-02-21, 1389/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of lateral internal sphincterotomy and botulinum toxin injection in treatment of chronic anal fissure

Public title

Comparison of lateral internal sphincterotomy and botulinum toxin injection in treatment of chronic anal fissure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of chronic anal fissure (presented greater than 6 weeks), presence of triad of (sentinel pile, hypertrophy of papi and fibrosis of bed wound), age between 18 and 100 years old
Exclusion criteria: combination with other anal diseases such as: hemorrhoid, anal fistula, rectal prolapse and positive history of anorectal surgery, positive history of neuromuscular diseases (myasthenia gravis, multiple sclerosis, amiotrophic lateral sclerosis), breast feeding,

pregnancy, positive history of drug consumption consist of aspirin, warfarin, aminoglycosides, chloroquine, aminoglycosides, chloroquine

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Medical Science

Street address

Shahid Fahmideh street

City

Hamedan

Postal code

Approval date

2010-08-14, 1389/05/23

Ethics committee reference number

57236/9/35/16پ

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 and two months after discharge

Method of measurement

Complete Wound Healing

Secondary outcomes

1

Description

complications

Timepoint

One week and two month after discharge

Method of measurement

Standard form

Intervention groups

1

Description

Intervention group: the patients set in knee chest position and single dose of botax, under local anesthesia is injected (25units) in internal sphincter in situation of 3 and 9 o'clock.

Category

Treatment - Drugs

2

Description

Control group: the patients set in trendelenberg position and under general anesthesia about 30 percent of internal muscle sphincter (in 3 o'clock situation) was ligated with knife (number 15)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Depatment of Surgery-Besat Hospital

Full name of responsible person

Dr Hamid Reza Fereidoonian

Street address

Besat bolvar

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- chancellor for Reasearch of Hamedan University of Medical Sciences

Full name of responsible person

Dr Hamid Reza Fereidoonian

Street address

shahid fahmideh street

City

Hamedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice- chancellor for Reasearch of Hamedan 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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Position

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Web page address

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