Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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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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 between18 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 (myesthenia 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 sitution 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 oclock sitution) 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
Resident of surgery

Other areas of specialty/work

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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