

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

+98 81 1264 0049

##### Email address

h.fereidoonian@umsha.ac.ir

##### 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 (myesthesia 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 oclock 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**

Dr Hamid Reza Fereidoonian

**Position**

Resident of surgery

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*