

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparative outcomes of botulinum toxin and Sphincterotomy in treatment of chronic anal fissure

#### Protocol summary

##### Summary

The aim of this study is comparison of the effect of botulinum toxin and Sphincterotomy in treatment of chronic anal fissure. This is nonblind clinical trial study. Patients with history of chronic anal fissure; skin tag or visible fibers of internal muscles of anal on bottom of ulcer will be included and acute anal fissure; fistula; inflammatory bowel disease; history of anal surgery; pregnancy will be excluded. After explaining the objectives of the study and obtaining the informed consent, patients randomized to random block 4-way A and B are divided two treatment group. one group with botulinum toxin and the second group with Sphincterotomy will be treated. Wound healing no pain during defecation are study out comes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081429352N1**

Registration date: **2016-09-10, 1395/06/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-10, 1395/06/20

##### Registrant information

##### Name

Ehsan Gharib

##### Name of organization / entity

Islamic Azad University Shahrood Branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3223 7331

##### Email address

ehsan-gharib@iau-shahrood.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahrood Islamic Azad University

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative outcomes of botulinum toxin and Sphincterotomy in treatment of chronic anal fissure

##### Public title

Effect of botulinum toxin and Sphincterotomy in treatment of anal fissure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: history of chronic anal fissure; skin tag or visible fibers of internal muscles of anal on bottom of ulcer exclusion criteria: acute anal fissure; fistula; inflammatory bowel disease; history of anal surgery; pregnancy

##### Age

No age limit

##### Gender

Both

##### Phase

3

##### Groups that have been masked

No information

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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 Shahroud University of Medical Sciences

##### Street address

Shahroud University of Medical Sciences, Hafte Tir Square, Shahroud

##### City

Shahroud

##### Postal code

3614773955

##### Approval date

2015-04-08, 1394/01/19

##### Ethics committee reference number

930/33

## 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

1,2,4,8 and then monthly for 6 month after treatment

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Pain During Defecation

#### Timepoint

1,2,4,8 and then monthly for 6 month after treatment

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Botulinum toxin 25 unit, injection, single dose

#### Category

Treatment - Drugs

### 2

#### Description

Sphincterotomy

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein Hospital

##### Full name of responsible person

Dr Fateme Amir KHalili

##### Street address

Imam Hussein Hospital, Imam Hussein Square, Shahroud

##### City

Shahroud

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Shahrood Islamic Azad University

##### Full name of responsible person

Dr Sahebali Manafi

##### Street address

Shahrood Islamic Azad University, Tehran Blvd, Shahroud

##### City

Shahroud

##### 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, Shahrood Islamic Azad University

**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**

Islamic Azad University of Shahroud

**Full name of responsible person**

Ehsan Gharib

**Position**

Medical Student

**Other areas of specialty/work**

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Fateme Amir khalili

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Gynecologist

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**Fax**

**Email**

**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*