

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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Phone

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Email address

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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**

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Full name of responsible person

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Medical Student

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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