Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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Islamic Azad University Shahrood Branch
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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 Hospial, 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

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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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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