

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Partial Lateral Internal Sphincterotomy Versus Combined Botulinum Toxin A Injection and Topical Application of Diltiazem in treatment of chronic anal fissure

#### Protocol summary

##### Summary

Objectives: A randomized control trial is performed to compare efficacy and complications of combined topical diltiazem (DTZ) gel and botulinum toxin A injection (BTA) versus partial lateral internal sphincterotomy (PLIS).management of chronic anal fissure remains a challenging issue. PLIS provides high cure rate with the expense of considerable risk of incontinence. DTZ and BTA have been widely used for medical sphincterotomy. However, no study has compared the effectiveness of combined DTZ and BTA with PLIS.Setting: This study conducts at Sina hospital. Design and intervention: 99 patients will randomly assigned to receive combined topical DTZ ointment and BTA injection or partial lateral internal incterotomy (PLIS) . Participants including major eligibility criteria: Diagnosis of chronic anal fissure on physical examination (based on having indurations at the edges and having at least two criteria of these three including skin tag, hypertrophied anal papillae and exposed internal sphincter muscle fiber) by an experienced colorectal surgeon associated with painful defecation for at least 2 month. Main outcome measure variables: Efficacy and complications following each treatment will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013042812294N3**

Registration date: **2013-10-21, 1392/07/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-10-21, 1392/07/29

#### Registrant information

##### Name

Reza Heydari

##### Name of organization / entity

School of Medicine, Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7780 7967

##### Email address

heydari@student.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

#### Expected recruitment start date

2010-03-21, 1389/01/01

#### Expected recruitment end date

2012-03-20, 1391/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Partial Lateral Internal Sphincterotomy Versus Combined Botulinum Toxin A Injection and Topical Application of Diltiazem in treatment of chronic anal fissure

#### Public title

Partial Lateral Internal Sphincterotomy Versus Combined Botulinum Toxin A Injection and Topical Application of Diltiazem in Treatment of Chronic Anal Fissure

#### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: diagnosis of chronic anal fissure on physical examination (based on having indurations at the edges and having at least two criteria of these three including skin tag; hypertrophied anal papillae and exposed internal sphincter muscle fiber) by an experienced colorectal surgeon associated with painful defecation for at least 2 month; age between 18 and 100 years old. Exclusion criteria: acute anal fissure (experiencing symptoms less than two months); pregnancy; secondary anal fissure; hypersensitivity to DTZ or BTA; cardiovascular disease; previous history of anal surgery; atypical fissure and chronic headache.

### **Age**

From **18 years** old to **100 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **99**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single 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 Tehran University of Medical Sciences.

##### **Street address**

1136746911, Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

##### **City**

Tehran

##### **Postal code**

1136746911

#### **Approval date**

2012-09-16, 1391/06/26

#### **Ethics committee reference number**

911301304

## **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, 1,2,6 and 12 months postoperatively

#### **Method of measurement**

Complete Wound Healing (macroscopic epithelialization)

## **Secondary outcomes**

### **1**

#### **Description**

complications

#### **Timepoint**

, one week, 1,2,6,12 months postoperatively

#### **Method of measurement**

physical examination and history taking, VAS

### **2**

#### **Description**

Induration, hypertrophied papilla, exposing internal anal sphincter, skin tag

#### **Timepoint**

before and after surgery

#### **Method of measurement**

physical examination

### **3**

#### **Description**

pain

#### **Timepoint**

before treatment, 1 week, 1,2,6 and 12 months postoperatively

#### **Method of measurement**

visual analog scale

### **4**

#### **Description**

chronicity of fissure

#### **Timepoint**

before treatment

#### **Method of measurement**

history taking

## 5

### **Description**

fissure localization

### **Timepoint**

before treatment

### **Method of measurement**

physical examination

## 6

### **Description**

bleeding

### **Timepoint**

before treatment, 1 week, 1,2,6 and 12 months  
postoperatively

### **Method of measurement**

history taking

## 7

### **Description**

pain at night

### **Timepoint**

before treatment, 1 week, 1,2,6 and 12 months  
postoperatively

### **Method of measurement**

history taking

## 8

### **Description**

recurrence

### **Timepoint**

1 ,2,6 and 12 month postoperatively

### **Method of measurement**

history taking and physical examination

## **Intervention groups**

### 1

#### **Description**

Intervention group: Under local anesthesia (with lidocaine 5% gel) on left sided or knee elbow position. BTA is injected into the internal anal sphincter on the both sides of anterior midline in equal doses. These patients will be advised to receive 2% DTZ ointment three times daily for six weeks which applied to the perianal region and anus.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: under spinal anesthesia in the lithotomy position; internal sphincter muscle fibers were partially cut at 3 o'clock position under direct visualization with a transverse incision up to the height of the fissure apex using a cautery. In this study, skin tags and hypertrophied anal papillae were also removed.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sina Hospital

##### **Full name of responsible person**

Dr Ahmadi-amoli

##### **Street address**

1136746911, Sina Hospital, Hasanabad Sq.,Tehran

##### **City**

Tehran

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Tehran University of  
Medical Sciences

##### **Full name of responsible person**

Dr.Akbar Fotouhi

##### **Street address**

1417613151, Tehran University of Medical Sciences,  
Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

##### **City**

Tehran

#### **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, Tehran 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**

Tehran University of Medical Sciences, Medical School

##### **Full name of responsible person**

Reza Heydari

##### **Position**

Medical student

##### **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*