

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of Botox and Nitroglycerin Ointment on Anal Fissure Repair

#### Protocol summary

##### Study aim

Effect of Botox and Nitroglycerin Rubber Ointments on Anal Fissure Repair to Suitably Replace for Anal Fissure Surgery

##### Design

This clinical trial has two parallel independent intervention groups, without control group, not blind. Thirty eight patients with Anal fissure are non-randomly divided (classified) into two equal groups, regardless of their age and sex. The study phase is 2-3.

##### Settings and conduct

The study will be conducted at Vali Asr training center in Arak. The sampling method will be continuous referral. Patients with chronic fissure syndrome can be included in the study. Patients will be randomly divided into two equal groups. For 6 weeks. This study is not blind.

##### Participants/Inclusion and exclusion criteria

All patients referred to Vali-e-Asr hospital in Arak during the course of the project, who are seeking treatment for chronic anal fissure. Inclusion criteria: patients who are suffering from chronic anal fissure. Exit condition: Patients who have incarcerated wounds. Patients who are pregnant. Patients who are allergic to the ointments used in this project. Patients who have previously undergone anal fissure surgery. Patients who will undergo fissure surgery during treatment with ointment for any reason.

##### Intervention groups

Intervention group (A) use nitroglycerin ointment and intervention group (B) use botox ointment 2 times daily for 12 hours for 6 weeks. During this 6-week period, patients will receive 3 tubes of ointment. e.

##### Main outcome variables

Pain, hematoma

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161017030336N7**

Registration date: **2020-03-30, 1399/01/11**

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

Last update: **2020-03-30, 1399/01/11**

Update count: **0**

##### Registration date

2020-03-30, 1399/01/11

##### Registrant information

###### Name

Ghasem Habibi

###### Name of organization / entity

Islamic azad university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3367 3208

###### Email address

dr.habibi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-02, 1398/12/12

##### Expected recruitment end date

2020-05-02, 1399/02/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Botox and Nitroglycerin Ointment on Anal Fissure Repair

##### Public title

Comparison of Botox and Nitroglycerin Ointment on Anal Fissure Repair

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with chronic anal fissure disease

### Exclusion criteria:

Patient dissatisfaction. Having incarcerated wounds. Pregnancy. Allergies to the ointments used in this scheme. Patients who had previously undergone Fischer anal Patients undergoing Fischer's anal surgery for any reason.

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: 38

## Randomization (investigator's opinion)

N/A

## 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 Arak University of Medical Sciences

##### Street address

Basidj Bridge, Sadasht

##### City

Arak

##### Province

Markazi

##### Postal code

3819693345

#### Approval date

2020-03-02, 1398/12/12

#### Ethics committee reference number

IR.ARAKMU.REC.1398.287

## Health conditions studied

### 1

#### Description of health condition studied

Chronic Anal fissure

#### ICD-10 code

K60.1

#### ICD-10 code description

Chronic anal fissure

### 2

#### Description of health condition studied

Acute anal fissure

#### ICD-10 code

K60.0

#### ICD-10 code description

Acute anal fissure

### 3

#### Description of health condition studied

Anal fissure, unspecified

#### ICD-10 code

K60.2

#### ICD-10 code description

Anal fissure, unspecified

### 4

#### Description of health condition studied

Abscess of anal and rectal regions

#### ICD-10 code

K61

#### ICD-10 code description

Abscess of anal and rectal regions

## Primary outcomes

### 1

#### Description

Inflammation at the wound site

#### Timepoint

Before intervention, 7, 14 and 28 days after intervention

#### Method of measurement

In-person examination

### 2

#### Description

Pain in the wound site

#### Timepoint

Before intervention, 7, 14 and 28 days after intervention

#### Method of measurement

Visual Anxiety Scale Questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group (A) will use 0.2% Nitroglycerin or Glycerin Trinitrate ointment made by Caspian Tamin Pharmaceutical Company at the wound site, twice daily for 12 hours for 6 weeks. During this 6-week period, patients will use 3 tubes of ointment. Patients are followed up in the first week, second week, fourth week and sixth month after treatment. Nitroglycerin ointment helps to cure fissile disease by lowering sphincter muscle pressure and increasing blood flow. The most important complication after using this ointment is headache and hypotension.

### Category

Treatment - Drugs

## 2

### Description

Intervention group (B) will use Botox ointment at the wound site, twice daily for 12 hours for 6 weeks. During this 6-week period, patients will use three ointment tubes. Follow-up is done in the first week, second week, fourth week and six months after treatment. Botox ointment can help treat this condition. In some cases, it can be injected to relieve pain when using other therapies. This procedure is performed using botulinum toxin to the wound. This toxin causes paralysis of the sphincter muscle for a limited time. This can relieve muscle cramps, or spasm, and relieve the pain of the patient. In addition, this toxin can also help repair the fissure caused by fissures.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Vali Asr Training Center of Arak

#### Full name of responsible person

Dr.Hossein Anari

#### Street address

Vali Asr Square

#### City

Arak

#### Province

Markazi

#### Postal code

3814957558

#### Phone

+98 86 3222 2003

#### Fax

+98 86 3222 2003

#### Email

pr\_valieasr@arakmu.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr.Alireza Kamali

#### Street address

Sardasht, Basidj Bidge

#### City

Arak

#### Province

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#### Postal code

3819693345

#### Phone

+98 86 3417 3505

#### Email

alikalaliir@yahoo.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Arak University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr.Hossein Anari

#### Position

Resident of Surgery

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Surgery

#### Street address

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#### Province

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**Email**

h.anari@arakmu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr.Siamak Rakei

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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**Phone**

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siamakrakei53@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ghasem Habibi

**Position**

Research Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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ghasemhabibi.chem@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available