

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

Markazi

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

Vali Asr Square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

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

Street address
Vali Asr Square

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3222 2003

Email
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

Pardis of Arak University of Medical Sciences,
Sardasht, Basidj Bidge

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

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