Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
alikamaliir@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