Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

comparing the effect of the Ansil gel with placebo on the treatment of acute Anal fissure

Protocol summary

Study aim
evaluating the effect of ANSIL in the treatment of acute anal fissure

Design
A randomized, double-blind, placebo-controlled phase 2_3 clinical trial with a parallel group on 50 patients. Randomization will be done in a simple way and with the Graphpad program.

Settings and conduct
This study is a double-blind, randomized, placebo-controlled study using Silver nitrate Gel or placebo Gel.The subjects are randomly assigned in a1:1 ratio in intervention or control groups. Patients referred to the Gastroenterology clinics with signs and symptoms of anal fissure are included in the study or are excluded from the study through the entry/exit criteria and if informed consent is given. Blinding method: Containers for a gel that has an active silver nitrate ingredient and a placebo gel are completely identical in terms of the shape and size, and the gels themselves do not differ in terms of odor and color. Identical tubes were labeled as A and B. In blinding, patient and the data analyzer will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Acute Anal fissure that is detected by direct observation or rigid anoscopy or flexible colonoscopy. Exclusion criteria: Existence of lateral fissure/ Patients with ANSIL allergy/Pregnancy/Taking any topical anal medication during the last 7 days

Intervention groups
Intervention:0/2% ANSIL gel twice a day for two weeks Control:Treating in a way other than the mentioned procedure

Main outcome variables
-Anal itching -Anal bleeding -Anal pain at rest -Anal pain during defecation -Pulse sensation after defecation -Feeling of a mass around the anus Bleeding from the fissure during the examination - Pain at the Fissure site during the examination

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190701044062N10**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date
2022-02-19, 1400/11/30

Registrant information
Name
manouchehr khoshbaten
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 1334 3010
Email address
mkhoshbaten@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-18, 1400/01/29
Expected recruitment end date
2022-06-19, 1401/03/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

comparing the effect of the Ansil gel with placebo on the treatment of acute Anal fissure

Public title
Effects of ANSIL in the treatment of anal fissures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 65 years old cases with Anal fissure symptoms and diagnosis of Anal fissure whithout emergency interventions based on physical examination Do not use any drug other than the drug under study and the placebo for treatment of Anal fissure during the study period
Exclusion criteria:
chronic Anal fissure lateral fissure the period of pregnancy or breastfeeding
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done in a simple way and using Graphpad software. Each group will be given the numbers A and B and The software will then generate random codes and based on those codes, patients will be provided with the desired drugs.
Blinding (investigator's opinion)
Double blinded
Blinding description
A gel that has an active ingredient in silver nitrate with a gel that does not have a substance and is used as a placebo is completely identical in terms of the shape and size of the container, and the gels themselves do not differ in terms of odor and color, and are completely indistinguishable. The important point is that the patient is told that the gel used for the patient may be medication or medication.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Tabriz university of medical sciences
Street address
central office of tabriz university of medical sciences Tabriz,Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5165663755
Approval date
2021-04-18, 1400/01/29
Ethics committee reference number
IR.TBZMED.REC.1400.045

Health conditions studied

1

Description of health condition studied
acute Anal fissure
ICD-10 code
K60.0
ICD-10 code description
Acute anal fissure

Primary outcomes

1

Description
Anal Fissure healing
Timepoint
at baseline and 2 week after the intervention
Method of measurement
physical examination and health history

Secondary outcomes

1

Description
Anal itching
Timepoint
at baseline and 2 week after the intervention
Method of measurement
health history

2

Description
anal bleeding
Timepoint
at baseline and 2 week after the intervention
Method of measurement
health history

3

Description
Anal pain at rest
Timepoint
at baseline and 2 week after the intervention
Method of measurement
شرح حال گیری

4

Description
anal pain during defecation
Timepoint
at baseline and 2 week after the intervention
Method of measurement
health history

5

Description
pulse sensation after defecation
Timepoint
at baseline and 2 week after the intervention
Method of measurement
health history

6

Description
feeling of a mass around the anus
Timepoint
at baseline and 2 week after the intervention
Method of measurement
health history

7

Description
bleeding of the fissure during the examination
Timepoint
at baseline and 2 week after the intervention
Method of measurement
physical examination

8

Description
Pain at the Fissure site during the examination
Timepoint
at baseline and 2 week after the intervention
Method of measurement
physical examination

Intervention groups

1

Description
Intervention group:0/2% Ansil gel (Silver Nitrate) which is made using the nanoparticle mechanism at Tabriz University of Iran and is applied to the wound for two weeks, twice a day in the size of a fingertip. The patient is taught for 15 to 30 minutes by an experienced and trained expert.
Category
Treatment - Drugs

2

Description
Control group: These are the group that take placebo Gel that has no therapeutic properties. It is worth mentioning that the participants in this project are patients with acute anal fissure that placebo was used for this group. We remind you that according to the inclusion criteria, patients should not have used any topical anal drug for at least the last 7 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Noore Nejat Hospital
Full name of responsible person
Manouchehr Khoshbaten
Street address
Hafez street
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tabriz
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Postal code
1416883834
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ata Mahmodpour
Street address
Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5154751637
Phone
+98 41 3337 2084
Email
a.mahmoodpour@gmail.com
Grant name

Tabriz University of Medical Sciences

Grant code / Reference number

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

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Manouchehr Khoshbaten

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Postal code

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Part of the data, which includes information about the main outcome and results, will be shared.

When the data will become available and for how

long

5 months after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data will be available to researchers and university professors for the studies of the meta - analysis

From where data/document is obtainable

Email: mh.hejazad@gmail.com

What processes are involved for a request to access data/document

Request via email: mh.hejazad@gmail.com As soon as possible

Comments