Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and comparison of therapeutic results of acyclovir in the treatment and improvement of anal fissure in non-herpes simplex virus patients and control group

Protocol summary

Study aim
Evaluation of therapeutic results of acyclovir in the treatment and improvement of anal fissure in non-herpes simplex virus patients

Design
A clinical trial with the control group, with cross-groups, double-blind, randomized, phase 3 on 120 patients. To randomize the rand list version 2.00 will be used.

Settings and conduct
Patients will enter the study after obtaining informed consent and explaining the process of the study. A clinical examination will be performed every week to assess the healing of the fissure based on the numerical rating scale pain assessment system. The Short form-36 quality of life evaluation system will be used to evaluate. If healing is seen, the patient will be evaluated for relapse every month.

Participants/Inclusion and exclusion criteria
The present study is a clinical trialو in which the statistical population of the study is all patients referred to the clinic of Imam Reza Hospital. According to previous studies, the sample size is considered to be 120 people which will be selected via software. Inclusion criteria included: patients with a clinical diagnosis of anal fissure, adults over 18 years of age, informed consent of patients to participate in the study, no previous history or current herpes simplex virus (HSV) infection, and other sexually transmitted diseases (STD). Exclusion criteria include: having a previous or current history of HSV and other STDs involving the perianal area, patient dissatisfaction to participate in the study.

Intervention groups
Patients are divided into 2 groups of 60 people. A group of 60 people called the control group is given well-known anti-fisher drugs such as diltiazem. The experimental group (including 60 people) will be given acyclovir ointment every 3 hours for 7 days.

Main outcome variables
Alterations in the severity of pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200906048636N1**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-29, 1400/10/08**
Update count: **0**

Registration date
2021-12-29, 1400/10/08

Registrant information
Name
Ali Farbod
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3554 0860
Email address
ali.frbd@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-12-06, 1400/09/15
Expected recruitment end date
2022-05-20, 1401/02/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of therapeutic results of acyclovir in the treatment and improvement of anal fissure in non-herpes simplex virus patients and control group

Public title

acyclovir in anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients' informed consent to participate in the study No previous or current history of HSV and other STDs Adults over the age of 18 Referral patients with clinical diagnosis of anal fissure

Exclusion criteria:

Have a previous or current history of HSV and other perinatal STDs Patient dissatisfaction to participate in the study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Rand list version 1.2 Software

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are divided into 2 groups of 60 people. A group of 60 people called the control group is given known anti-fisher drugs such as diltiazem and the experimental group (including 60 people) will be used acyclovir ointment to treat anti-fissure. Patients' clinical history will be reviewed by phone every day and every week in the clinic and all information will be recorded in the attached questionnaire.

Placebo

Not 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

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.TBZMED.REC.1400.821

Health conditions studied

1

Description of health condition studied

Anal fissures

ICD-10 code

K60.2

ICD-10 code description

Anal fissure, unspecified

Primary outcomes

1

Description

Pain relief assessed based on numerical rating scale (NRS)

Timepoint

before intervention and 2, 3 , 4, 8, 12 weeks after intervention

Method of measurement

Checklist based on NRS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First group receiving acyclovir ointment as treatment of anal fissure

Category

Treatment - Drugs

2

Description
Control group: Second group receiving common treatment (diltiazem ointment) of the anal fissure
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hosital
Full name of responsible person
Ali Farbod
Street address
Imam Reza Hospital, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 7054
Email
imamreza@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ata Mahmoodpour
Street address
Tabriz University of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
+98 41 3336 4667
Email
amahmoodpoor@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
Ali Farbod
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Imam Reza Hospital, Golgasht street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
0098413331317
Email
ali.frbd@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Farbod
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Imam Reza Hospital, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 4334 1317
Email
Ali.frbd@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Ali Farbod

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

Street address
Imam Reza Hospital, Golgasht Street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Phone
0098413331317

Email
ali.frbd@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All the data including age, sex, history of STD (such as HSV), and the type of treatment used, will be shared anonymously.

When the data will become available and for how long
Data will be accessible 6 months following publication of the results

To whom data/document is available
Our documentations will be accessible for academic researchers.

Under which criteria data/document could be used
Any analysis of the data is approved.

From where data/document is obtainable
Ali Farbod

What processes are involved for a request to access data/document
The data will be accessible a maximum of 2 weeks after applying via email to Ali.frbd@gmail.com

Comments