

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 trial, 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

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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

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5166616471

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Farbod

Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Email

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ali Farbod

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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City

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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

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