Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of cutaneous advancement flap and mucosal advancement flap as a surgical treatment for chronic anal fissure

Protocol summary

Study aim
to compare The rate of fissure healing and recurrence and the extent of pain and suffering in two groups of patients with chronic fissure by two surgical methods with cutaneous advancement flap and mucosal advancement flap

Design
This study is a single-blind randomized clinical trial on 30 patients divided into two equal groups and records patient demographics, postoperative pain scores using the Visual Analogue Scale (VAS) method, and Complications and results are reviewed prospectively

Settings and conduct
The study of a single-blind randomized clinical trial on patients with chronic anal fissure referred to Imam Khomeini Hospital. Cutaneous advancement flap and mucosal advancement flap surgery for chronic fissure were performed on two groups of patients who were randomly divided.

Participants/Inclusion and exclusion criteria
diagnosed with chronic anal fissure and not responding to medication therapy and a candidate for surgery

Intervention groups
Intervention groups 1: Surgery of patients with anal fissure by Cutaneous advancement flap method
Intervention groups 2: Surgery of patients with anal fissure by mucosal advancement flap method

Main outcome variables
The rate of the healing and recurrence of fissures and the evaluation of the pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120129008861N4**
Registration date: **2022-01-23, 1400/11/03**
Registration timing: **registered_while_recruiting**
Last update: **2022-01-23, 1400/11/03**
Update count: **0**

Registration date
2022-01-23, 1400/11/03

Registrant information

Name
Mohammad Reza Keramati

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-05, 1400/03/15

Expected recruitment end date
2022-06-05, 1401/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of cutaneous advancement flap and mucosal advancement flap as a surgical treatment for chronic anal fissure

Public title
Comparison of cutaneous advancement flap and mucosal advancement flap as a surgical treatment for chronic anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a chronic anal fissure that has not responded to drug treatment and is a candidate for surgery

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Randomization; Random unit: Individual; Randomization tool: excel Randomization tool output: The patient enters the surgical group with cutaneous advancement flap or mucosal advancement flap.

Blinding (investigator's opinion)

Single blinded

Blinding description

30 patients with chronic anal fissure are randomly divided into two groups: cutaneous advancement flap and mucosal advancement flap surgery. This study is a randomized clinical trial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences ethics committee

Street address

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran, Iran

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1417613151

Approval date

2021-05-19, 1400/02/29

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.058

Health conditions studied

1

Description of health condition studied

chronic anal fissure

ICD-10 code

K60.1

ICD-10 code description

Chronic anal fissure

Primary outcomes

1

Description

Chronic anal fissure

Timepoint

Postoperative pain and bleeding 1 day, 1 week, 1 month after surgery

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: surgery with cutaneous advancement flap

Category

Treatment - Surgery

2

Description

Second Intervention group: surgery with mucosal advancement flap

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mohamad Reza Keramati

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End of Keshavarz Blvd,Tehran,Iran

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data will be shared after blinding of datasheet.
When the data will become available and for how long
Data will be shared within 6 months after publication.
To whom data/document is available
Data will be accessible for researchers affiliated to universities
Under which criteria data/document could be used
Data can be used for further meta-analysis after permission of the person responsible for this project.
From where data/document is obtainable
Data request should be sent through email for the person responsible for this project. Dr. Mohammad Reza Keramati mr-keramati@tums.ac.ir
What processes are involved for a request to access data/document
Following the primary request, all the researchers will be informed by the responsible person and after permission the data will be shared.
Comments