

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

mr-keramati@razi.tums.ac.ir

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

City

Tehran

Province

Tehran

Postal code

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

Sponsor

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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

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Keramati
Position
Associate Professor of Surgery
Latest degree
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Other areas of specialty/work
General Surgery

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Person responsible for updating data

Contact

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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