Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the results of chronic anal fissure surgery between conventional internal partial sphincterotomy and tailored sphincterotomy of string suture anoscope

Protocol summary

Study aim
Comparison of the results of chronic anal fissure surgery between conventional internal partial sphincterotomy and tailored sphincterotomy of string suture anoscope

Design
A single-blind, randomized clinical trial study with parallel groups and phases 3 on 60 patients. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct
This study will be conducted in patients with chronic anal fissure undergoing surgery inUrmiaImam Khomeini Hospital.Patients will be randomly assigned to one of two groups: conventional partial internal sphincterotomy or tailored sphincterotomy. The study will be a single-blinded study.

Participants/Inclusion and exclusion criteria
Patients with a history of chronic anal fissure lasting more than one month will be included in the study. The main exclusion criteria will be acute fissures, coexicted fissure with fistula or inflammatory bowel disease, a history of systemic diseases, a history of anal surgery (for fissure, fistula, or hemorrhoids), fecal incontinence.

Intervention groups
Patients will be randomly assigned via block randomization into Conventional partial internal sphincterotomy or tailored sphincterotomy. In conventional Sphincterotomy, 30% of the exposed internal sphincter will be cut. The incision site will be repaired with absorbable sutures and dressed. In tailored Sphincterotomy group , a No. 34 purse-string anoscope will be inserted and rotated circumferentially. Any areas of tightness will be incised using electrocautery. The fissure will be assessed, and thickened edges or apical skin tags (if present) will be excised. The surgeon will ensure that the electrocautery does not extend beyond the dentate line. The extent of sphincterotomy will be precisely adjusted based on fissure height.

Main outcome variables
Complete treatment of Fischer; fecal incontinence, gas incontinence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210919052515N6**
Registration date: **2025-06-20, 1404/03/30**
Registration timing: **prospective**

Last update: **2025-06-20, 1404/03/30**
Update count: **0**

Registration date
2025-06-20, 1404/03/30

Registrant information

Name
Naser Masoudi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 44 3337 9924

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-23, 1404/05/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the results of chronic anal fissure surgery between conventional internal partial sphincterotomy and tailored sphincterotomy of string suture anoscope

Public title

Comparison of the two methids of conventional internal partial sphincterotomy and tailored sphincterotomy of string suture anoscope in chronic anal fissure surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-65 old years Chronic anal fissure lasting more than one month Exhibiting signs of chronicity upon anal examination such as the presence of a skin tag Vsible fibers of the internal anal sphincter at the base of the wound

Exclusion criteria:

Patients with acute fissures Coexicted fissure with fistula or inflammatory bowel disease A history of systemic diseases A history of anal surgery (for fissure, fistula, or hemorrhoids) Fecal incontinence Perineal tears following delivery Prior radiotherapy Use of corticosteroids or other immunosuppressive drugs pregnant women

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two methods of surgery using block randomization based on generated numbers by random allocation software. So that, in this software, the number of groups and the total number of the sample size will be entered and then in the block section, the block randomization method will be implemented. Patients will be allocated to two groups based on generated numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be conducted as a single-blind clinical trial. The patient will be blinded about surgery methods.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini Hospital, Urmia University of Medical Sciences

Street address

Imam Khomeini hospital, Ershad street, Modarres Blvd., Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-81351

Approval date

2025-03-12, 1403/12/22

Ethics committee reference number

IR.UMSU.HIMAM.REC.1403.139

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

Complete treatment of Fischer

Timepoint

Weeks one, four, eight, and 6 months after surgery

Method of measurement

Clinical examination

2

Description

Gas incontinence

Timepoint

Weeks one, four, eight, and 6 months after surgery

Method of measurement

Questioning the patient

3

Description

Fecal incontinence

Timepoint

Weeks one, four, eight, and 6 months after surgery

Method of measurement

Questioning the patient

Secondary outcomes

1

Description

Pain score

Timepoint

After surgery during recovery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Dosage of analgesia

Timepoint

24 hours after surgery

Method of measurement

Milligram

Intervention groups

1

Description

Intervention group: In tailored Sphincterotomy group , a No. 34 purse-string anoscope will be inserted and rotated circumferentially. Any areas of tightness will be incised using electrocautery. The fissure will be assessed, and thickened edges or apical skin tags (if present) will be excised. The surgeon will ensure that the electrocautery does not extend beyond the dentate line. The extent of sphincterotomy will be precisely adjusted based on fissure height.

Category

Treatment - Surgery

2

Description

Control group: . In conventional partial Sphincterotomy, 30% of the exposed internal sphincter will be cut. The incision site will be repaired with absorbable sutures and dressed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini hospital

Full name of responsible person

Dr. Naser Masoudi

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Imam Khomeini hospital., Ershad street., Modarres Blvd., Urmia, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Naser Masoudi

Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No further information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable