

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

comparing the results and complications of chronic anal fissure surgery between open surgical sphincterotomy and closed surgical sphincterotomy

Protocol summary

Study aim

Comparing the results and complications of chronic anal fissure surgery between open and closed surgical sphincterotomy

Design

In this prospective randomized clinical trial performed in Arak Valiasr hospital, all patients with chronic anal fissure who failed to respond to medical therapy after two weeks will be included and those who have recurrent chronic anal fissure or concomitant anorectal disease including anal fistula, abscess and malignancy, inflammatory bowel disease or those who fail to return for follow up are excluded. Patients will be assigned into two groups. Patients in first group will undergo closed partial lateral internal sphincterotomy and patients in second group will undergo open partial lateral internal sphincterotomy. Cure rate and complications including post operative pain, hemorrhage and infection are recorded and patients will be followed for six months.

Settings and conduct

In this study which will be performed in Arak Valiasr hospital, first group of patients will undergo closed partial lateral internal sphincterotomy. In this procedure while nondominant index finger of surgeon is inserted in anal canal, number eleven surgical blade is inserted at dermal-anodermal junction distal to dentate line at three o'clock lithotomy position, then blade is rotated laterally and retracted with forty five degrees lateral deviation. Patients in the second group will undergo open surgery. In this procedure an incision, half to one centimeters long, is made on dermal-anodermal junction in inter sphincteric plane and internal sphincter is delivered to wound using a curved hemostat clamp and one third to one half of sphincter bulk is incised and the remainder is released to retract. In both procedures, sufficiency of sphincterotomy and intactness of rectal mucosa is ascertained by digital examination and wound is

hemostased and closed with chromic 00 sutures.

Participants/Inclusion and exclusion criteria

All patients with chronic anal fissure will be included; Patients who have recurrent chronic anal fissure, concomitant anorectal disease and inflammatory bowel disease will be excluded.

Intervention groups

In first group patients will undergo Closed partial lateral internal sphincterotomy; in the second group patients will undergo Open partial lateral internal sphincterotomy. Cure rate after surgery will be assessed and compared among groups.

Main outcome variables

wound cure rate; pain; hemorrhage; infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171023036968N1**

Registration date: **2018-01-13, 1396/10/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-13, 1396/10/23**

Update count: **0**

Registration date

2018-01-13, 1396/10/23

Registrant information

Name

sasan habib akhyari

Name of organization / entity

arak medical university

Country

Iran (Islamic Republic of)

Phone

+98 31 3345 7941

Email address

Recruitment status

Recruitment complete

Funding source

arak medical university

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the results and complications of chronic anal fissure surgery between open surgical sphincterotomy and closed surgical sphincterotomy

Public title

comparing the results and complications of chronic anal fissure surgery between open surgical sphincterotomy and closed surgical sphincterotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with chronic anal fissure who failed to respond to medical therapy after two weeks

Exclusion criteria:

recurrent chronic anal fissure or concomitant anal disease including anal fistula, abscess, malignancy and inflammatory bowel disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Not randomized

Randomization description

patients are randomi

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's committee of Arak Medical University

Street address

Arak Medical University, basij square, Arak, Markazi province

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2017-10-08, 1396/07/16

Ethics committee reference number

IR.ARAKMU.REC.1396.107

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

wound cure rate

Timepoint

fourth and twelfth post operative days and six months after surgery

Method of measurement

clinical examination for assessing healing of fissure and surgical site wound

2

Description

post operative pain

Timepoint

first and fourth and twelfth post operative days

Method of measurement

screening with a 0-10 pain intensity Numeric Rating Scale

3

Description

post operative hemorrhage

Timepoint

first post operative day

Method of measurement

number of blood drenched gauzes of wound dressing during first post operative day

4**Description**

post operative infection

Timepoint

first, fourth and twelfth post operative days

Method of measurement

examination for signs of cellulitis, wound discharge, induration and necrosis

Secondary outcomes

empty

Intervention groups**1****Description**

first Intervention group: in this group patients will undergo closed partial lateral internal sphincterotomy. In this procedure while nondominant index finger of surgeon is inserted in anal canal, number eleven surgical blade is inserted at dermal-anodermal junction distal to dentate line at three o'clock lithotomy position, then blade is rotated laterally and retracted with forty five degrees lateral deviation. sufficiency of sphincterotomy and intactness of rectal mucosa is ascertained by digital examination and wound is hemostased and closed with chromic 00 sutures.

Category

Treatment - Surgery

2**Description**

Secound Intervention group: in this group patients will undergo open surgery. In this procedure an incision, half to one centimeters long, is made on dermal-anodermal junction in inter sphincteric plane and internal sphincter is delivered to wound using a curved hemostat clamp and one third to one half of sphincter bulk is incised and the remainder is released to retract. sufficiency of sphincterotomy and intactness of rectal mucosa is ascertained by digital examination and wound is hemostased and closed with chromic 00 sutures.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center**

Name of recruitment center

Arak Valiasr hospital

Full name of responsible person

Dr. Sasan Habib Akhyari

Street address

Department of General Surgery, Valiasr hospital, Valiasr square, Arak, Markazi perovince

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Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

s.habibakhyari@arakmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Reza Jafari, B.Sc.

Street address

Post box 646, Alam Al Hoda st, Shiroudi st, Arak

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr. Sasan Habib Akhyari

Position

resident of general surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Web page address**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak Medical University

Full name of responsible person

Dr. Sasan Habib Akhyari

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available