

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 mounths 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
City
Arak
Province
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
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3313 6055
Email
s.habibakhyari@arakmu.ac.ir
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

Street address

General Surgery Department, Valiasr hospital, Valiasr square, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax**Email**

s.habibakhyari@arakmu.ac.ir

Web page address**Web page address****Person responsible for updating data****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**Street address**

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

City

Arak

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Markazi

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Phone

+98 86 3222 2003

Fax**Email**

s.habibakhyari@arakmu.ac.ir

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

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Other areas of specialty/work

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Street address

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

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax**Email**

s.habibakhyari@arakmu.ac.ir

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