Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, abcess and malignancy, inflammatory bowell 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 secound 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 mounths.

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 prosedure 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 fourty five degrees lateral deviation. patients in the secound 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 bowell disease will be excluded.

Intervention groups

in first group patients will undergo Closed partial lateral internal sphincterotomy؛ in the secound 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

s.habibakhyari@arakmu.ac.ir

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, abcess, malignancy and inflammatory bowell 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 prosedure 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 fourty 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

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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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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Other areas of specialty/work
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Person responsible for updating data

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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