Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Two Methods of Hemorrhoid Surgery: Stapled Hemorrhoidectomy and Conventional Surgery on Patients Clinical Outcomes

Protocol summary

Study aim
Comparison of two methods of hemorrhoid surgery: stapled hemorrhoidectomy and conventional surgery on patients clinical outcomes
Design
Clinical trial with a control group and sample size of 40 people allocated randomly by random number table in two groups of intervention and control.
Settings and conduct
Study was conducted in the department of surgery in Ahvaz Razi Hospital. In the intervention group, patients underwent stapled hemorrhoidectomy and in comtrol group patients underwent conventional hemorrhoidectomy surgery. Finally, the clinical outcomes are compared with the standard instruments in both groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria:patients aged 18 to 60 years and patients with grade 3 or 4 internal hemorrhoids. Exclusion criteria: thrombosed hemorrhoids, drug addiction, history of previous anorectal surgery and fisher or an anal fistula
Intervention groups
Intervention group: patients in this group undergo stapled hemorrhoidectomy. Control group: Patients in this group underwent conventional hemorrhoidectomy.
Main outcome variables
Pain; Anal sphincter pressure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170610034428N1**
Registration date: **2019-06-08, 1398/03/18**
Registration timing: **retrospective**
Last update: **2019-06-08, 1398/03/18**
Update count: **0**
Registration date
2019-06-08, 1398/03/18

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 84 3372 2282
Email address
ghiasi.h@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-06-25, 1396/04/04
Expected recruitment end date
2017-12-02, 1396/09/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Two Methods of Hemorrhoid Surgery: Stapled Hemorrhoidectomy and Conventional Surgery on Patients Clinical Outcomes

Public title
Stapled Hemorrhoidectomy on Patients Clinical Outcomes
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 60 years Patients with grade 3 or 4 internal hemorrhoids

Exclusion criteria:

Thrombosed hemorrhoids Drug addiction History of previous anorectal surgery Fisher or an anal fistula

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Block. Block size =4. possible ways = 6. Permuted block randomization=15. Block selection numbers with random numbers table. Unit randomization: individual. A person who specifies the sequence is the executor of plan not the surgeon,the designer must hide the information from the surgeon.

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2017-08-28, 1396/06/06

Ethics committee reference number

IR.AJUMS.REC.1396.205

Health conditions studied

1

Description of health condition studied

hemorrhoid

ICD-10 code

K64.1

ICD-10 code description

Second degree hemorrhoids

Primary outcomes

1

Description

pain

Timepoint

One, two and three days after surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Anal sphincter pressure

Timepoint

Before surgery and one month after surgery

Method of measurement

Anal manometer

Intervention groups

1

Description

Intervention group: patients in this group undergo stapled hemorrhoidectomy. This is done in 5 steps and in the following order: 1. Slow anal canal dilatation for inserting the device with a dilator. 2. Speculum insertion. 3. Creata a pure-String Suture. 4. Insert Stapler. 5. Bleeding control in the anastomosis line.

Category

Treatment - Surgery

2

Description

Control group: patients in this group underwent conventional hemorrhoidectomy.In this procedure, the entire pocket is removed and the mucosa is close to the cut line and the rest of the skin wounds are kept open.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Neda Najibpour

Street address
Razi hospital, Palestin Blv, Amanieh

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Ahvaz

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razi.hospital@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad Badavi (Deputy of Research and Technology of University)

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

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badavi.m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Heydar Ghiasi

Position
Resident of surgery

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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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 more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available