

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 control 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

Khuzestan

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. Create 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

City

Ahvaz

Province

Khuzestan

Postal code

15794-61357

Phone

+98 61 3333 5935

Email

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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+98 61 3337 4598

Email

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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Person responsible for updating data

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

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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