

# 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

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Phone**

+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

**Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Blvd

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Phone**

+98 61 3337 4598

**Email**

ghiasi.h@ajums.ac.ir

## Person responsible for scientific 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**

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+98 61 3337 4598

**Email**

ghiasi.h@ajums.ac.ir

## 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**

General Surgery

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**City**

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**Province**

Khouzestan

**Postal code**

61357-15794

**Phone**

+98 61 3337 4598

**Email**

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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