

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of open hemorrhoidectomy versus hemorrhoidectomy with electrocautery on inter-postoperative signs in patients with hemorrhoid grade 3 and 4

#### Protocol summary

##### Summary

Objective: comparison of two methods of open hemorrhoidectomy using electrocautery; Study design: randomized single-blind, placebo-uncontrolled, single-center, phase II trials; Study population: all patients with hemorrhoid referring to the surgery clinic; Inclusion criteria: hemorrhoids grade 3 or 4 which is proven by clinical examination, aged between 15 and 50 years, surgical indication; Exclusion criteria: history of previous anal surgery, diseases such as anal fissure or fistula, some degree of incontinency, thrombosed hemorrhoids, history of anticoagulant intake, coagulation disorders, patients with anesthesia prohibiton, addiction, the same disease that causes pain; Sample size: 60; Interventions: The first group included 30 patients will be treated by open hemorrhoidectomy, the second group of 30 patients will be treated with electrocautery hemorrhoidectomy procedures; Outcomes: the mean of pain in the first day after surgery, need for analgesic injection on the first day, hospitalization period, time to return to daily activities, pain in the first week and first month after surgery, bleeding after surgery, postoperative urinary retention, subcutaneous abscess, surgical site infection, anal fissure after surgery, gas or stool incontinancy after surgery, fistula after surgery, recurrence after surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016072028993N2**

Registration date: **2016-08-21, 1395/05/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-21, 1395/05/31

##### Registrant information

###### Name

Ehsan Rahimi

###### Name of organization / entity

Zahedan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3329 5580

###### Email address

dr.ehsanrahimi@zaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2016-08-05, 1395/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of open hemorrhoidectomy versus hemorrhoidectomy with electrocautery on inter-postoperative signs in patients with hemorrhoid grade 3 and 4

##### Public title

Comparison of open hemorrhoidectomy versus

hemorrhoidectomy with electrocautery in patients with hemorrhoid

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: hemorrhoids grade 3 or 4 which is proven by clinical examination; aged between 15 and 50 years; surgical indication; Exclusion criteria: history of previous anal surgery; diseases such as anal fissure or fistula; some degree of incontinency; thrombosed hemorrhoids; history of anticoagulant intake; coagulation disorders; patients with anesthesia prohibition; addiction; similar disease presents as hemorrhoid pain.

### **Age**

From **15 years** old to **50 years** old

### **Gender**

Both

### **Phase**

1-2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Block randomized in blocks of six and a total of 10 blocks

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Zahedan Medical University of Science

##### **Street address**

Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Zahedan

##### **City**

Zahedan

##### **Postal code**

#### **Approval date**

2010-09-23, 1389/07/01

#### **Ethics committee reference number**

IR.zaums.rec.1394.177

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Haemorrhoid

#### **ICD-10 code**

I84, I84.4

#### **ICD-10 code description**

Haemorrhoids

## **Primary outcomes**

### **1**

#### **Description**

Operation duration

#### **Timepoint**

Since the start of the operation until its end

#### **Method of measurement**

Minute

### **2**

#### **Description**

Interoperation bleeding

#### **Timepoint**

Based on the number of impregnated gauze

#### **Method of measurement**

Number

### **3**

#### **Description**

Postoperation bleeding

#### **Timepoint**

One week, one month, three months, six months after surgery

#### **Method of measurement**

Based on physical examination and patients statement

### **4**

#### **Description**

Need for intravenous analgesic

#### **Timepoint**

First day after surgery

#### **Method of measurement**

Number

### **5**

#### **Description**

Hospitalization period

#### **Timepoint**

From admission to discharge

#### **Method of measurement**

Day

### **6**

#### **Description**

Postoperation pain

**Timepoint**

Up to 24 hours after surgery in intervals of every 4 hours

**Method of measurement**

VAS Criteria

**7****Description**

Postoperation urinary retention

**Timepoint**

One week, one month, three months, six months after surgery

**Method of measurement**

Based on physical examination and patients statement

**8****Description**

Subcutaneous abscess

**Timepoint**

One week, one month, three months, six months after surgery

**Method of measurement**

Based on physical examination and patients statement

**9****Description**

Surgery site infection

**Timepoint**

One week, one month, three months, six months after surgery

**Method of measurement**

Based on physical examination and patients statement

**10****Description**

Anal fissure

**Timepoint**

One week, one month, three months, six months after surgery

**Method of measurement**

Based on physical examination and patients statement

**11****Description**

Anal stricture

**Timepoint**

One week, one month, three months, six months after surgery

**Method of measurement**

Based on physical examination and patients statement

**12****Description**

Fistula

**Timepoint**

One week, one month, three months, six months after surgery

**Method of measurement**

Based on physical examination and patients statement

**13****Description**

Recurrence

**Timepoint**

One week, one month, three months, six months after surgery

**Method of measurement**

Based on physical examination and patients statement

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: open surgical hemorrhoidectomy

**Category**

Treatment - Surgery

**2****Description**

Control group: hemorrhoidectomy using electrocautery

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ali-ebn Abi Taleb Hospital, Zahedan

**Full name of responsible person**

Ehsan Rahimi

**Street address**

Surgery Department, Ali-ebn Abi Taleb Hospital, Salamat Boulevard, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

**City**

Zahedan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Zahedan University of Medical Sciences

**Full name of responsible person**

Mohsen Taheri

**Street address**

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

**City**

Zahedan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Zahedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Zahedan Medical University

**Full name of responsible person**

Ehsan Rahimi

**Position**

Surgery Residence

**Other areas of specialty/work**

**Street address**

Surgery Department, Ali-ebn Abi Taleb Hospital, Salamat Boulevard, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

**City**

Zahedan

**Postal code**

**Phone**

+98 54 3329 5583

**Fax**

**Email**

dr.ehsanrahimi@zaums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zahedan Medical University

**Full name of responsible person**

Dr. Alireza Khazaei

**Position**

Associate Professor of Surgery

**Other areas of specialty/work**

**Street address**

Surgery Department, Ali-ebn Abi Taleb Hospital, Salamat Boulevard, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

**City**

Zahedan

**Postal code**

**Phone**

+98 54 3329 5583

**Fax**

**Email**

dr.alirezakhazaie@zaums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Ehsan Rahimi

**Position**

Infectious Diseases Residence

**Other areas of specialty/work**

**Street address**

Surgery Department, Ali-ebn Abi Taleb Hospital, Salamat Boulevard, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

**City**

Zahedan

**Postal code**

**Phone**

+98 54 3329 5794

**Fax**

**Email**

dr.ehsanrahimi@zaums.ac.ir

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*