Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 prohibiton; 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
Recurrance
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

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Alireza Khazaee

Position

Associate Professor of Surgery

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Infectious Diseases Residence

Other areas of specialty/work

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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