

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of the Effect of internal sphincterotomy in wound healingrate and post operative pain after open hemorrhoidectomy

Protocol summary

Summary

Objective: Evaluation the effect of internal sphincterotomy on wound healing rate and the pain after open hemorrhoidectomy surgery in Semnan Kowsar hospital Study design: single blinded randomized clinical trial study, without placebo control population: Patients with grade III and IV hemorrhoid referred to Kowsar hospital in order to surgery and they only need to remove a hemorrhoid gland Inclusion criteria: Patients aged 20-70 years with grade III and IV hemorrhoid referred to Kowsar hospital in order to surgery and they only need to remove a hemorrhoid gland Exclusion criteria: history of previous anal surgery; patients with Anal Fissure; patients with Anal Fistula; patients with Anal Abscess; incarcerated hemorrhoid and or thrombosis; pregnancy; patients who need to few hemorrhoids lump surgery; patients with other Anal abnormalities; taking anticoagulants and antiplatelet drugs; history of inflammatory bowel disease (IBD); addicted patients Sample size, intervention, intervention time and outcome of study: Sample size of this study is 40 persons will be divided into intervention and control groups. Intervention group: Intervention group included patients who are undergoing to open hemorrhoidectomy surgery with internal sphincterotomy. All surgeries are performed under general anesthesia and open surgery. Also in all cases hemorrhoids vascular basement are closed with chromium yarn 0.2. Control group: Control group include just patients who are undergoing to open hemorrhoidectomy surgery and just the results is used to compare with experimental group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081325732N25**

Registration date: **2017-10-15, 1396/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of internal sphincterotomy in wound healingrate and post operative pain after open hemorrhoidectomy

Public title

Evaluation of the Effect of internal sphincterotomy in wound healingrate and post operative pain after open hemorrhoidectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 20-70 years with grade III and IV hemorrhoid referred to Kowsar hospital in order to surgery and they only need to remove a hemorrhoid lump. Exclusion criteria: History of previous anal surgery; patients with Anal Fissure; patients with Anal Fistula; patients with Anal Abscess; incarcerated hemorrhoid and or thrombosis; pregnancy; patients who need to few hemorrhoids lump surgery; patients with other Anal abnormalities; taking anticoagulants and antiplatelet drugs; history of inflammatory bowel disease (IBD); addicted patients.

Age

From **20 years** old to **70 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

Blinding (investigator's opinion)

Single 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 Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

semnan

Postal code

3514799442

Approval date

2017-07-12, 1396/04/21

Ethics committee reference number

IR.SEMUMS.REC.1396.102

Health conditions studied

1

Description of health condition studied

Hemorrhoidectomy

ICD-10 code

I84.2

ICD-10 code description

Internal haemorrhoids without complication

Primary outcomes

1

Description

Postoperative pain

Timepoint

12 hours after surgery and once at the time discharge

Method of measurement

Questionnaire (based on Visual Analog Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Control group include just patients who are undergoing to open hemorrhoidectomy surgery.

Category

Diagnosis

2

Description

Intervention group: Intervention group included patients who are undergoing to open hemorrhoidectomy surgery with internal sphincterotomy. All surgeries are performed under general anesthesia and open surgery. Also in all cases hemorrhoids vascular basement are closed with chromium yarn 0.2.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Setareh Soltany

Street address

Amin Blvd, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Semnan University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Asgari

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Semnan University of Medical Sciences, Basij Blvd, Semnan

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Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research and Technology, Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Setareh Soltany

Position

General surgeon

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Email**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