Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

Iran (Islamic Republic of)

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+98 23 3345 1336

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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
City
Semnan

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
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
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
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Setareh Soltany
Position
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Person responsible for updating data

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Fax
+98 23 3344 8950
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