Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of pain and bleeding after hemorrhoidopexy with stapler and excisional hemorrhoidectomy in internal hemorrhoid surgery

Protocol summary

Study aim
Comparison of pain and bleeding after hemorrhoidopexy with stapler and excisional hemorrhoidectomy in internal hemorrhoid surgery

Design
This is a clinical trial study with parallel groups; single blind; randomized phase 3 on 98 patients. Patients will be grouped into groups A and B based on the Randomization Block Balanced method. The name of each surgical technique will be placed in boxes A and B.

Settings and conduct
This study aimed to compare the mean pain score and evaluate the volume of bleeding occurring after internal hemorrhoid surgery between two groups (hemorrhoidopexy with stapler and excisional hemorrhoidectomy) in the Kashani Hospital in Shahrekord. Only the responsible physician (supervisor) and the project executor are aware of the contents of each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with indications necessitating internal hemorrhoids surgery who were referred to Kashani Hospital in Shahrekord during the years 1403-1404; Informed consent to participate in the research study; Age between 18-65 years old; Not being contraindications for surgery. Exclusion criteria: Patients who have a previous history of undergoing hemorrhoid surgery; Patients who have a history of bleeding disorders or consumption of anticoagulant medications; Patients who have a history of inflammatory bowel diseases or colorectal cancer; Patients who have been banned from consuming general anesthesia or spinal anesthesia.

Intervention groups
The Intervention groups: The first group: Excisional hemorrhoidectomy surgery was performed. The second group: Hemorrhoidopexy with stapler was performed.

Main outcome variables
Pain; Bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250105064277N1**
Registration date: **2025-01-30, 1403/11/11**
Registration timing: **prospective**

Last update: **2025-01-30, 1403/11/11**
Update count: **0**

Registration date
2025-01-30, 1403/11/11

Registrant information
Name
Rasoul Rahimi
Name of organization / entity
Country
Iran (Islamic Republic of)
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rahimi.r@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

Expected recruitment end date
2025-07-23, 1404/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of pain and bleeding after hemorrhoidopexy with stapler and excisional hemorrhoidectomy in internal hemorrhoid surgery

Public title
Comparison of pain and bleeding after hemorrhoidopexy with stapler and excisional hemorrhoidectomy in internal hemorrhoid surgery
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with indications necessitating for internal hemorrhoids surgery who referred to Kashani Hospital in Shahrekord during the years 1403-1404 Informed consent to participate in the research study. Age between 18-65 years old Not being contraindications for surgery
Exclusion criteria:
Patients who have a previous history of undergoing hemorrhoid surgery. Patients who have a history of bleeding disorders or consumption of the anticoagulant medications. Patients who have a history of inflammatory bowel diseases or colorectal cancer. Patients who have been banned from consumeing general anesthesia or spinal anesthesia.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be grouped into groups A and B based on the Randomization Block Balanced method. The name of each surgical method will be placed in boxes A and B. Only the responsible physician (supervisor) and the project executor are aware of the contents of each group, and each patient will be randomly assigned Iinto one box.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the responsible physician (supervisor) and the project executor are aware of the contents of each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Kashani Street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2024-12-25, 1403/10/05
Ethics committee reference number
IR.SKUMS.MED.REC.1403.096

Health conditions studied

1

Description of health condition studied
Hemorrhoidopexy
ICD-10 code
H11.41
ICD-10 code description
Vascular abnormalities of conjunctiva

Primary outcomes

1

Description
Pain
Timepoint
The assessment of the mean pain score utilizing the Visual Analog Scale (VAS) at the onset of the investigation (before the initiation of the intervention) and intervals of 24, 48, and 72 hours post-operatively following internal hemorrhoid surgery
Method of measurement
VAS Questionnaire

2

Description
Bleeding
Timepoint
Evaluating the volume of bleeding occurring during the surgical procedure and 7 days after internal hemorrhoid surgery
Method of measurement
Using blood-saturated gauze (each piece of gauze typically absorbs around 20 cc of blood).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group: Excisional hemorrhoidectomy surgery was performed.
Category
Diagnosis

2

Description
Intervention group: The second group: Hemorrhoidopexy with stapler was performed.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Dr Rasoul Rahimi
Street address
Kashani Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Seyed Mohammad Omrani
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Rasoul Rahimi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
No - There is not a plan to make this available