

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

+98 38 3333 0061

Email address

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 consuming 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 into 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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Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

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Email

Rahimi.r@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Seyed Mohammad Omrani

Street address

Kashani Street

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Shahrekord

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Chahar-Mahal-va-Bakhtiari

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8815713271

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omranism@skums.ac.ir

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

General Surgery

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Person responsible for scientific 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**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

General Surgery

Street address

Kashani Street

City

Shahrekord

Province**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