

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A comparative study of the effect of jackknife and lithotomy positions on the process and complications of hemorrhoidectomy surgery

Protocol summary

Study aim

Compare the effect of lithotomy and jackknife positions on the amount of bleeding, duration of surgery, postoperative pain, the exposure of the operative site from surgeon's point of view, and the local discomfort of the surgeon to adapt himself to the surgical field.

Design

A parallel two-group clinical trial involving 60 patients

Settings and conduct

The present research will be conducted on patients undergoing hemorrhoidectomy in Besat hospital, Hamadan, in 2023. In this study, there is no possibility of blinding and the study is conducted in an open-label manner. The researcher will visit the operating room department of Besat hospital in two shifts, morning and evening, and informed consent will be obtained from the patients. Then, after grouping the patients into two groups randomly, the desired variables will be measured.

Participants/Inclusion and exclusion criteria

The criteria for entering this study include: age between 15 and 60 years old; suffering from grade 3 or 4 hemorrhoid disease and informed consent to participate in the study. Also exclusion criteria include: presence of thrombosed hemorrhoids; drug addiction; use of anticoagulants; history of previous anorectal surgery; presence of fissure or anal fistula and lack of consent to participate in a research project.

Intervention groups

Considering that the majority of hemorrhoidectomy surgeries are performed using the lithotomy position therefore, we will consider the lithotomy group as the control group and the jackknife group as the intervention group. Hemorrhoidectomy is considered at the beginning of surgery.

Main outcome variables

Surgical time; intraoperative bleeding; postoperative pain; the exposure of the operative site from surgeon's point of view and surgeon's local discomfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230129057271N1**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Sina Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3320 8792

Email address

sinaghasemi19980@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of jackknife and lithotomy positions on the process and complications of hemorrhoidectomy surgery		Name of ethics committee Research Ethics Committee of Hamadan University of Medical Sciences	
Public title A comparative study of the effect of jackknife and lithotomy positions on the process and complications of hemorrhoidectomy surgery		Street address 4th Floor, Vice-Chancellor for Research and Technology, University Headquarters, Shahid Fahmideh Blvd.	
Purpose Treatment		City Hamadan	
Inclusion/Exclusion criteria Inclusion criteria: Age range between 15 and 60 years old Having grade 3 or 4 hemorrhoids Informed consent to participate in the study Exclusion criteria: The presence of thrombosed hemorrhoids Drug addiction Taking anticoagulants History of previous anorectal surgery The presence of fissure or anal fistula Lack of consent to participate in the research project		Province Hamadan	
		Postal code 6517838678	
		Approval date 2023-01-28, 1401/11/08	
		Ethics committee reference number IR.UMSHA.REC.1401.940	
Health conditions studied			
<u>1</u>			
Description of health condition studied hemorrhoids			
ICD-10 code K64			
ICD-10 code description Hemorrhoids and perianal venous thrombosis			
Primary outcomes			
<u>1</u>			
Description Duration of surgery			
Timepoint From the moment of positioning the patient to the moment of placing the dressing on the surgical site			
Method of measurement Using a minute counter to measure surgery time			
<u>2</u>			
Description The amount of bleeding during the operation			
Timepoint During surgery			
Method of measurement Using a scale to measure the amount of bleeding during surgery			
<u>3</u>			
Description The amount of pain after the operation			
Timepoint One day, three days, seven days and two weeks after surgery			
Method of measurement Using the NRS criterion			

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Age From 15 years old to 60 years old	
Gender Both	
Phase N/A	
Groups that have been masked <i>No information</i>	
Sample size Target sample size: 60	
Randomization (investigator's opinion) Randomized	
Randomization description Allocation of patients in two groups will be done in random blocks so that; The block size is equal to 4. The randomization tool in this research will be the use of four envelopes containing two sheets j and two sheets l, each time by removing one of the sheets, the patient will be placed in the jackknife or lithotomy group. The removed sheets will not be returned to the envelope until the 4 sheets are finished. After determining the assignment of the first 4 patients, the sheets are returned to the envelope and the next 4 patients will continue in this way until the sample size is completed.	
Blinding (investigator's opinion) Not blinded	
Blinding description	
Placebo Not used	
Assignment Parallel	
Other design features	
Secondary Ids empty	
Ethics committees	
<u>1</u>	
Ethics committee	

4

Description

The amount of local discomfort for the surgeon

Timepoint

After surgery

Method of measurement

Using the LPD scale

5

Description

The exposure of the operative site from surgeon's point of view

Timepoint

After surgery

Method of measurement

5-point Likert scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the allocation of jackknife position during the start of hemorrhoidectomy surgery is considered.

Category

Treatment - Surgery

2

Description

Control group: In this study, the lithotomy position is routinely used for the control group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital, Hamadan city

Full name of responsible person

Sina Ghasemi

Street address

Hokama Street

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Province

Hamadan

Postal code

4541165148

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohi

Street address

Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6517838736

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Email

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sina Ghasemi

Position

Master of science student

Latest degree

Master

Other areas of specialty/work

Surgical technologist

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Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available