Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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

Purpose
Treatment

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

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

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

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences

Street address
4th Floor, Vice-Chancellor for Research and Technology, University Headquarters, Shahid Fahmideh Blvd.

City
Hamadan

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

1

Description of health condition studied
hemorrhoids

ICD-10 code
K64

ICD-10 code description
Hemorrhoids and perianal venous thrombosis

Primary outcomes

1

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

2

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

3

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

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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Postal code
4541165148
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Email
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Web page address
https://besat.umsha.ac.ir/

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
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6517838736
Phone
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Email
vc_research@umsha.ac.ir
Web page address
https://www.umsha.ac.ir/
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 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