

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

###### **City**

Hmadan

###### **Province**

Hamadan

###### **Postal code**

4541165148

###### **Phone**

+98 81 3265 0030

###### **Email**

besat@umsha.ac.ir

##### **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**

Hamadan

###### **Province**

Hamadan

###### **Postal code**

6517838736

###### **Phone**

+98 81 3131 0000

###### **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 scientific inquiries

### Contact

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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