

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of simple closure versus Limberg flap on initial repair in patients with sacrococcygeal pilonidal sinus: a randomized clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of simple closure versus Limberg flap on initial repair in patients with sacrococcygeal pilonidal sinus. Design: A randomized clinical trial. Setting and conduct: The eligible patients with sacrococcygeal pilonidal sinus who will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 65 years; sacrococcygeal pilonidal sinus. Exclusion criteria: Infection of abscess in the area of pilonidal sinus; previous history of pilonidal sinus surgery. Intervention group 1: Excision of cyst of pilonidal sinus and then repairing surgical area by simple and routine method. Intervention group 2: Excision of cyst of pilonidal sinus and then repairing surgical area by Limberg flap method. Primary outcome: Wound repair one week and then 1, 3 and 23 months after surgery through physical examination. Secondary outcome: Assessing pain 3 and 6 hours after surgery by Visual Analog Scale (VAS). Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201710109014N195**  
Registration date: **2017-10-19, 1396/07/27**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-19, 1396/07/27

##### Registrant information

Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research and Technology, Hamadan  
University of Medical Sciences

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of simple closure versus Limberg flap on initial repair in patients with sacrococcygeal pilonidal sinus: a randomized clinical trial

##### Public title

Effect of simple closure versus Limberg flap on initial repair in patients with sacrococcygeal pilonidal sinus

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 65 years; sacrococcygeal pilonidal sinus. Exclusion criteria: Infection of abscess in the area of pilonidal sinus; previous history of pilonidal

sinus surgery.

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **76**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Postal code

#### Approval date

2017-06-17, 1396/03/27

#### Ethics committee reference number

IR.UMSHA.REC.1396.251

## Health conditions studied

### 1

#### Description of health condition studied

Sacrococcygeal pilonidal sinus

#### ICD-10 code

L05

#### ICD-10 code description

Pilonidal cyst

## Primary outcomes

### 1

#### Description

Wound repair

#### Timepoint

One week and then 1, 3 and 23 months after surgery

#### Method of measurement

Through physical examination

## Secondary outcomes

### 1

#### Description

Assessing pain

#### Timepoint

3 and 6 hours after surgery

#### Method of measurement

By visual Analog Scale (VAS)

## Intervention groups

### 1

#### Description

Intervention group 1: Excision of cyst of pilonidal sinus and then repairing surgical area by simple and routine method.

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group 2: Excision of cyst of pilonidal sinus and then repairing surgical area by Limberg flap method.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Dr Abdollah Boostan Afrooz

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-chancellor for Research and Technology, Hamadan  
University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Besat Hospital

**Full name of responsible person**

Dr Abdollah Boostan Afrooz

**Position**

Resident of Surgery

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

**Contact**

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**Position**

Resident of Surgery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*