

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 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

Besat Hospital, Shahed Square

City

Hamadan

Postal code

Phone

+98 81 3364 0030

Fax

Email

dr_boostan@yahoo.com

Web page address

Person responsible for scientific 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

Besat Hospital, Shahed Square

City

Hamadan

Postal code

Phone

+98 81 3364 0030

Fax

Email

dr_boostan@yahoo.com

Web page address

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

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

Web page address

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