Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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

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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

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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

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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