Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the results of pilonidal sinus repair with methods of swing flap and secondary intension

Protocol summary

Study aim
Comparison of the results of Swing Flap surgery repair of pilonidal sinus with secondary repair

Design
Two arm parallel group non randomised trial with non-blinded postoperative care and outcome assessment

Settings and conduct
100 patients with pilonidal sinus referred to shohadaye ashayer hospital after examination and having the inclusion criteria and the absence of exclusion criteria are divided into two groups of 50, one group undergoing open surgery and one group undergoing Swing flap and then during six months follow-up based on a questionnaire and doctor's examination variables are examined

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Patients referring to Shohada-e-Ashayer and Rahimi Hospital in Khorramabad for pilonidal sinus surgery 2- Satisfaction to participate in the study Exclusion criteria: 1- People who have pilonidal sinus abscess 2- People with recurrence of the pilonidal sinus 3- Patients with purulent hydroadenitis in the sacrococcygeal area 4 - People who have risk factors for wound healing (such as iron deficiency anemia, malnutrition, immunodeficiency, diabetes and the use of corticosteroids and anti-metabolic drugs) 5- Pregnant women 6- Dissatisfaction to participate in the study

Intervention groups
Two groups of 50 patients are divided randomly. For one group, surgery with secondary repair method (The control group) and for the second group, surgery with swing flap (The intervention group) .

Main outcome variables
Body mass index, Type of surgery, Duration of surgery, Postoperative site infection, Amount and severity of hematoma and postoperative site bleeding, Site seroma, Flap necrosis, recurrence of the disease, Time interval between recurrence of the first surgery, Severity of postoperative site pain, Scarring Wound , Wound opening, Wound healing time, Return to daily work time and Patient satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210926052604N1**
Registration date: **2021-10-21, 1400/07/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-21, 1400/07/29**
Update count: **0**

Registration date
2021-10-21, 1400/07/29

Registrant information

Name
Seyed ahmad Seyed alagheband

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8801 5893

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ahmadalagheband@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-17, 1400/07/25

Expected recruitment end date
2021-11-01, 1400/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the results of pilonidal sinus repair with methods of swing flap and secondary intension

Public title
Comparison of the results of pilonidal sinus repair with methods of swing flap and secondary intension

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the study Patients referred to Shohada Ashayer Hospital in Khorramabad for pilonidal sinus surgery

Exclusion criteria:
Patient with pilonidal sinus abscess Patient with recurrence of the pilonidal sinus Patients with purulent hydroadenitis in the sacrococcygeal region Patient who have risk factors for wound healing (such as iron deficiency anemia, malnutrition, immunodeficiency, diabetes and the use of corticosteroids and anti-metabolic drugs) pregnant women

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Not randomized

Randomization description

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
Ethics committee of Lorestan university of medical sciences

Street address
Enghelab Blvd shohadaye ashayer hospital

City
Khorramabad

Province
Lorestan

Postal code
1438863184

Approval date
2020-12-29, 1399/10/09

Ethics committee reference number
IR.LUMS.REC.1399.259

Health conditions studied

1

Description of health condition studied
Pilonidal sinus

ICD-10 code
L05.92

ICD-10 code description
Pilonidal sinus without abscess

Primary outcomes

1

Description
Duration of operation

Timepoint
Operation time

Method of measurement
Time to minutes

2

Description
Postoperative site Infection

Timepoint
First week and Second weak after surgery

Method of measurement
Doctor examination

3

Description
Hematoma and postoperative bleeding

Timepoint
First week and second week after surgery

Method of measurement
Doctor examination

4

Description
Surgery site seroma

Timepoint
1week and 2week and 1month after surgery

Method of measurement
Doctor examination

5

Description

Flap necrosis

Timepoint

1weak and 2weak after surgery

Method of measurement

Doctor examination

6

Description

Recurrence of disease

Timepoint

3month and 6month after surgery

Method of measurement

Doctor examination

7

Description

Interval of recurrence of the disease from the first surgery

Timepoint

6 month after surgery

Method of measurement

Doctor examination

8

Description

Severity of postoperative position pain

Timepoint

1weak and 2weak and1month and 3month after surgery

Method of measurement

Visual analogue scale questionnaire

9

Description

Surgical site scar

Timepoint

1month and 6month after surgery

Method of measurement

Doctor examination

10

Description

Wound dehiscence

Timepoint

1weak and 2weak and 1month after surgery

Method of measurement

Doctor examination

11

Description

Time of wound healing

Timepoint

3month and 6month after surgery

Method of measurement

Doctor examinatiob

12

Description

Return time to daily work

Timepoint

1 month and 3month after surgery

Method of measurement

Questionnaire

13

Description

Postoperative satisfaction

Timepoint

6month after surgery

Method of measurement

Licrd satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pilonidal sinus repair by swing flap surgery. In this method, the wound repair by displacement of adjacent tissue after removig of pilonidal sinus.

Category

Treatment - Surgery

2

Description

Control group: pilonidal sinus repair by secondary method. the wound is left open and is not repaired In this method, after removing the pilonidal sinus.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye ashayer hospital

Full name of responsible person

Seyed-ahmad seyed-alagheband

Street address

Shohadaye ashayer hospital,Enghelab Blvd, khorramabad city

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ebrahim Falahi
Street address
3 km Khorramabad-Borujerd, University of Medical Sciences Complex, Vice Chancellor for Research and Technology
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1438863184
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+98 66 3312 0172
Email
e_falahi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Seyed-Ahmad Seyed-Alagheband
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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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