

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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)

Phone

+98 21 8801 5893

Email address

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

1week and 2week 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

1week and 2week and 1month 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

1week and 2week 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 examinatio

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

City

Khorramabad

Province

Lorestan

Postal code

1438863184

Phone

+98 66 3330 5006

Email

Ahmadalagheband@gmail.com

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

City

Khorramabad

Province

Lorestan

Postal code

1438863184

Phone

+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

Street address

Enghelab Blvd shohadaye ashayer hospital

City

Khorramabad

Province

Lorestan

Postal code

1438863184

Phone

+98 66 3330 5006

Email

Ahmadalagheband@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Seyed-ahmad seyed-alagheband

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Resident

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Medical doctor

Other areas of specialty/work

General Surgery

Street address

Enghelab Blvd Shohadaye ashayer hospital

City

Khorramabad

Province

Lorestan

Postal code

1438863184

Phone

+98 66 3330 5006

Email

Ahmadalagheband@gmail.com

Person responsible for updating data**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

Street address

Shohadaye ashayer hospital,Enghelab Blvd,khrramabad

City

Khorramabad

Province

Lorestan

Postal code

1438863184

Phone

0098 66 3305006

Email

Ahmadalagheband@gmail.com

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