Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Comparison of the outcome of two methods of pilonidal sinus surgery, tie-over and simple repair during 2023-2024 in patients admitted to Shahrekord Ayatollah Kashani Hospital.

Protocol summary

Study aim

Determining and comparing the results of two pilonidal sinus surgery methods, tie-over and simple repair, during 2023-2024 in patients admitted to Ayatollah Kashani Shahrekord Hospital.

Design

A single-blind clinical trial, with two intervention groups with a sample size of 220 people, in which each patient is randomly assigned to groups A and B. Group A undergoes pilonidal sinus surgery by tie-over method and group B undergoes pilonidal sinus surgery by simple repair method. This study was conducted from April 2023 to March 2024 and the patients will be followed up for 6 months. Randomization of patients is done by the researcher and based on the admission of patients in turn in each group A and B.

Settings and conduct

People who undergo pilonidal sinus surgery at Ayatollah Kashani Hospital in Shahrekord. After filing the hospitalization case, each patient goes to group A and B alternately, so that the first patient admitted after the start of the study is in group A and the next patient is in group B and continues in the same way until the last patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All male and female patients aged 15 to 50 who are diagnosed with sacral pilonidal sinus and complete the consent form. Exclusion criteria: patients with diabetes, weak immune system, cancer and collagen vascular disease.

Intervention groups

Patients who undergo pilonidal sinus surgery by tie-over method Patients who undergo pilonidal sinus surgery with a simple repair method

Main outcome variables

Comparing the results of pilonidal sinus surgery based on age, sex, occupation, marital status, post-operative pain, post-operative infection, recurrence rate, bleeding rate and patient satisfaction rate in two methods of pilonidal sinus surgery by tie-over method with a simple repair method.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240302061141N1**
Registration date: **2024-05-28, 1403/03/08**
Registration timing: **retrospective**

Last update: **2024-05-28, 1403/03/08**
Update count: **0**

Registration date

2024-05-28, 1403/03/08

Registrant information

Name

Behrooz Behzadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3623 7273

Email address

behbehzadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the outcome of two methods of pilonidal sinus surgery, tie-over and simple repair during 2023-2024 in patients admitted to Shahrekord Ayatollah Kashani Hospital.

Public title

Comparison of the outcome of two methods of pilonidal sinus surgery, tie-over and simple repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All male and female patients diagnosed with sacral pilonidal sinus The age of patients entering the study is 15 to 50 years Patients who have completed the consent form

Exclusion criteria:

Patients with diabetes Patients with weak immune system Patients with cancer Patients with collagen vascular disease

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **220**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are randomly and equally divided into two groups A (tie-over surgery) and B (simple repair surgery) (each patient goes to group A and B alternately After filing the hospital admission file, so that the first patient After the start of the study placed in group A and the next patient is placed in group B, and so on until the last patient. Due to the fact that the patients must be informed about the type of operation and due to the fact that the researcher will perform the surgery himself, blinding is not possible at this stage, but after collecting the samples and providing the information to the analyst, blinding will be done and analysis is done based on the first and second groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

No. 25, 26 Alley, Varzesh Ave.

City

Shahr-e-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815854476

Approval date

2024-04-06, 1403/01/18

Ethics committee reference number

IR.SKUMS.MED.REC.1403.004

Health conditions studied

1

Description of health condition studied

Pilonidal sinus

ICD-10 code

L05

ICD-10 code description

Pilonidal cyst and sinus

Primary outcomes

1

Description

Age of people by year

Timepoint

Knowing the patient's age when admitted to the hospital

Method of measurement

Hospital admission file

2

Description

Gender of the patient

Timepoint

Knowing the patient's gender when admitted to the hospital

Method of measurement

Hospital admission file

3

Description

Patient's job

Timepoint

Information about the patient's occupation at the beginning of the study

Method of measurement

through a questionnaire

4

Description

Marital status of the patient

Timepoint

At the beginning of the study when the patient was admitted

Method of measurement

Hospital admission file

5

Description

The amount of pain after surgery

Timepoint

Day 1 and day 6 after surgery

Method of measurement

through a questionnaire

6

Description

Postoperative wound infection

Timepoint

6th day and 6 months after surgery

Method of measurement

Clinical examination of the patient

7

Description

Recurrence of the disease

Timepoint

6 months after the operation

Method of measurement

Clinical examination of the patient

8

Description

Bleeding from the operation site

Timepoint

1 and 6 days after surgery

Method of measurement

Clinical examination of the patient

9

Description

Postoperative satisfaction rate

Timepoint

6 days and 6 months after surgery

Method of measurement

through a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: In the simple repair method, the pilonidal sinus is completely removed. After the hole is completely washed, a No. 14 hemovac drain will be inserted into the incision and exit from the upper part of the incision, and a cover will be used to suck blood from the wound. Then 0-2 Vicryl will be used to press the subcutaneous tissue together and the skin will be repaired using 0-3 nylon.

Category

Treatment - Surgery

2

Description

The second intervention group: First, an elliptical incision will be made on their skin and the sinus will be completely removed up to the perisacral fascia. Then, using a cover, the subcutaneous tissue and skin will be removed from the medius and two flaps will be created on both sides of the wound. After completely washing the hole and removing the blood using the cover, and if there is no bleeding, the skin and subcutaneous tissue and the entire presacral fascia will be sutured using 3 tension stitches using nylon 0-1, the cut in the upper and middle part will be sutured. . After this step, the freed flaps will be sutured together using absorbable suture (0-2 Vicryl). Then the subcutaneous tissue is brought together. In the last step, the layers of the skin are brought together using 0-3 nylon with round and close sutures so that the edges of the wound are overlapped.Then a bandage will be placed on the wound and it will be closed using tension stitches.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Ayatollah Kashani Hospital

Full name of responsible person

Behrooz Behzadi

Street address

Ayatollah Kashani Hospital, Parastar Blvd.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Behrooz Behzadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Questionnaire form and informed consent as well as clinical examination results that have been recorded
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
The data is accessible to researchers working in academic institutions
Under which criteria data/document could be used
The use of the delivered data is allowed only for a more detailed examination and to help choose the preferred method of pilonidal sinus surgery. Statistical analysis to help further research is allowed
From where data/document is obtainable
Dr Behrooz Behzadi Email : behbehzadi@yahoo.com mobile : 09137293913
What processes are involved for a request to access data/document
After contacting via e-mail or phone call or text message, after identifying the requester and ensuring that the data is not misused, the file containing the data will be sent to them.
Comments