

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

A comparative study of three open ,semi-closed, and closed surgical methods in the treatment of pilonidal sinus in terms of recovery time, side effects, and costs in the: A clinical trial double blinded.

Protocol summary

Study aim

Determining the comparative study of three open, semi-closed, and closed surgical methods for the treatment of pilonidal sinus disease in terms of recovery time, complications, and costs.

Design

This study was designed as a double-blind randomized trial that was conducted on patients Under pilonidal sinus surgery, referring to Imam Khomeini (RA) hospital, Poldakhtar, it will be performed with 3 open, closed and semi-closed methods in 1402

Settings and conduct

Imam Khomeini Hospital, Poldakhtar

Participants/Inclusion and exclusion criteria

The entry criteria were 1- a candidate for pilonidal sinus surgery and 2- not having a history of pilonidal sinus surgery 3- not having diabetes and malignancy and the exit criteria were 1- the patient's unwillingness to cooperate, 2- the inability to communicate.

Intervention groups

In this study, in patients who are candidates for pilonidal sinus surgery, the intervention will be in the form of 3 methods: 1- leaving the wound open, 2- bringing the layers of the wound closer together, 3- closing the wound in the middle line.

Main outcome variables

Bleeding, pain, infection, recovery time, costs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230409057866N1**

Registration date: **2023-04-27, 1402/02/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-27, 1402/02/07**

Update count: **0**

Registration date

2023-04-27, 1402/02/07

Registrant information

Name

somayh souri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3222 5108

Email address

sourisomayh88@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-12, 1402/01/23

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of three open ,semi-closed, and closed surgical methods in the treatment of pilonidal sinus in terms of recovery time, side effects, and costs in the: A clinical trial double blinded.

Public title

A comparative study of three open ,semi-closed, and closed surgical methods in the treatment of pilonidal

sinus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for pilonidal sinus surgery No history of pilonidal sinus surgery Not having diabetes and malignancy
Exclusion criteria:
The patient's unwillingness to cooperate The patient's inability to communicate

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
A table of random numbers is used for randomization. direction Using the table of random numbers first to read the numbers of the determination table Numbers will then be considered for different groups to be On one of the numbers and in one of the directions in advance Determined to move and assign numbers to different groups we give.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be double blinded. Patients according to the type The intervention (each of the three methods of open, semi-closed, and closed surgery for the treatment of pilonidal sinus) is blinded, as well as the researcher who must enter the data into the checklist. The subject will be blinded to the type of intervention.

Placebo
Not used

Assignment
Other

Other design features
In this study, there are three groups and each will receive only one different intervention and only at one time

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan

City

hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2023-04-07, 1402/01/18

Ethics committee reference number

IR.UMSHA.REC.1402.024

Health conditions studied

1

Description of health condition studied

Pilonidal sinus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Recovery time, pain, bleeding, infection, costs

Timepoint

during the intervention until one month after the intervention

Method of measurement

McGill questionnaire, Likert scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, in patients who are candidates for pilonidal sinus surgery, the intervention will be in the form of 3 methods: 1- leaving the wound open, 2- bringing the layers of the wound closer together, 3- and closing the wound in the middle line.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Poldakhtar

Full name of responsible person

Mohammad Hossein Ehsani
Street address
کوی بسیجیان، بیمارستان امام خمینی پلدختر
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
dr.behzad imani
Position

Associate Professor
Latest degree
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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data received from participants will remain confidential but general results will be published without individual identification

When the data will become available and for how long

After completion of the research is accessible

To whom data/document is available

General

Under which criteria data/document could be used

It seeks to reduce the problems faced by patients with the aim of reducing complications and costs and quickly returning to work and society.

From where data/document is obtainable

Refer to the selected journal where the data is published to access the data

What processes are involved for a request to access data/document

Introduction to how to search and access valid sites and magazines

Comments