

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of the results of pilonidal sinus surgery with Kardidakis flap method in comparison with open method

Protocol summary

Study aim

Evaluation of the results of pilonidal sinus surgery by Kardidakis flap method in comparison with open surgery method

Design

All patients referred to the surgical ward of Imam Reza Hospital in Mashhad with a diagnosis of pilonidal sinus during 1401-1402 undergo closed surgery by one surgeon and another by open method after obtaining informed consent and explaining the type of operation to the patient. After the operation, the first day in the ward and the first week in the clinic and the first month are examined by phone for recurrence, infection, pain at the operation site, etc., and then they are analyzed by statistical tests.

Settings and conduct

All patients referred to the surgical ward of Imam Reza Hospital in Mashhad with a diagnosis of pilonidal sinus during 1401-1402 undergo closed surgery by one surgeon and another by open method after obtaining informed consent and explaining the type of operation to the patient. After the operation, the first day in the ward and the first week in the clinic and the first month are examined by phone for recurrence, infection, pain at the operation site, etc., and then they are analyzed by statistical tests.

Participants/Inclusion and exclusion criteria

Patients with a diagnosis of pilonidal sinus disease
Patient with recurrence of pilonidal sinus disease

Intervention groups

In the group of patients who undergo the intervention, the surgery is performed with a closed method with the kardidakis flap.

Main outcome variables

Wound closure time / Patient pain / Wound infection /
Relapse / Time to return to work

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051862N1**

Registration date: **2022-04-29, 1401/02/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-29, 1401/02/09**

Update count: **0**

Registration date

2022-04-29, 1401/02/09

Registrant information

Name

Morteza Tavasolizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 4388

Email address

drmorteza20@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the results of pilonidal sinus surgery with Kardidakis flap method in comparison with open method

Public title
Evaluation of the results of pilonidal sinus surgery with Kardidakis flap method in comparison with open method in Imam Reza Hospital in 2022-2023

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a diagnosis of pilonidal sinus disease
Patient with recurrence of pilonidal sinus disease
Exclusion criteria:
Patients with pilonidal sinus abscess Patient non-cooperation Dissatisfaction with closed pilonidal sinus surgery Diseases such as diabetes, connective tissue disease, etc., which delay the healing time of the wound Patients taking corticosteroids, which delays wound healing time

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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 Mashhad University of Medical Sciences

Street address

Unit 4, No. 20, Panahi., Alley 6 , Amirieh Blvd
Mashhad

City

mashhad

Province

Razavi Khorasan

Postal code

9189963763

Approval date

2022-02-22, 1400/12/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.831

Health conditions studied

1

Description of health condition studied

Pilonidal Sinus Disease

ICD-10 code

L05

ICD-10 code description

Pilonidal cyst and sinus

Primary outcomes

1

Description

The amount of pain

Timepoint

The day after surgery and then one week and one month after surgery

Method of measurement

McGill Pain Questionnaire Observation and examination of patients

2

Description

Wound Infection

Timepoint

The day after surgery and then one week and one month after surgery

Method of measurement

Clinical observation

3

Description

Time to return to work

Timepoint

The day after surgery and then one week and one month after surgery

Method of measurement

Phone call

4

Description

Wound closure time

Timepoint

One month after surgery

Method of measurement

Patient examination

5

Description

Recurrence of the disease
Timepoint
One year after surgery
Method of measurement
Phone call

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, which is a closed surgery, after sterilizing the field with betadine, the pilonidal sinus site is marked with a marker, then to reduce bleeding into it, a solution of epinephrine diluted with -100 cc Sterile serum is injected. The operation site is removed with a razor blade and removed. After controlling the bleeding, a drain is placed in the wound floor to drain the wound, then the subcutaneous tissue and skin are repaired in three layers.

Category

Treatment - Surgery

2

Description

Control group: In this group, open surgery is performed in such a way that after sterilizing the surgical site with betadine, the sinus location is determined with the help of a marker and injection of die into it. Then, from the control of bleeding and washing the place with sterile serum, the place is bandaged with wet gas and left open.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Morteza Tavasolizade

Street address

Unit 4, No. 20, Panahi, Alley 6 , Amirieh Blvd,
Mashhad

City

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Postal code

9189963763

Phone

+98 51 4464 4388

Email

Drmorteza20@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ali Kiani

Street address

School of Medicine, Ferdowsi University Campus,
Vakilabad Blvd, Mashhad

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Postal code

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Fax

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Email

Drmorteza20@yahoo.com

Web page address

<https://mums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Morteza Tavassolizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Unit 4, No. 20, Panahi., Alley 6 , Amirieh Blvd
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Morteza Tavassolizadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Morteza Tavassolizadeh
Position
Residency
Latest degree
Medical doctor
Other areas of specialty/work

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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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study has not started yet

When the data will become available and for how long

The study has not started yet

To whom data/document is available

The study has not started yet

Under which criteria data/document could be used

The study has not started yet

From where data/document is obtainable

The study has not started yet

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

The study has not started yet

Comments

The study has not started yet