

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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

9189963763

## 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

## Approval date

2022-02-22, 1400/12/03

## Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.831

## 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

## 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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**Province**

Razavi Khorasan

**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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91177948974

**Phone**

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**Fax**

+98 51 3880 2700

**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**

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,Mashhad

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Drmorteza20@yahoo.com

## 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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Drmorteza20@yahoo.com

## Person responsible for updating data

### Contact

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

General Surgery  
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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