# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Nov 2026

## Comparison of Complication Rates Following Pilonidal Sinus Excision with Off-Midline Flap Repair Versus Simple Excision and Primary Closure: A Non-Randomized Quasi-Experimental Study with Historical Controls in Afzalipour and Shahid Bahonar Hospitals, Kerman

## Protocol summary

**Study aim**

To compare short-term complications and 6-month outcomes of pilonidal sinus excision with off-midline flap repair versus simple excision and primary closure.

**Design**

Two-center, non-randomized, non-blinded quasi-experimental study with a historical control group; census sampling; analysis with chi-square, Fisher's exact test and multivariable logistic regression in SPSS 27.

**Settings and conduct**

Afzalipour and Shahid Bahonar hospitals, Kerman. Control group data are extracted from medical records using a standardized checklist. Flap group patients are enrolled prospectively after informed consent and examined in the first postoperative days and at 30 days, 3 months and 6 months after surgery.

**Participants/Inclusion and exclusion criteria**

Inclusion: age 14–50 years; candidate for first-time pilonidal sinus surgery; informed consent. Exclusion: acute pilonidal abscess requiring emergency surgery; previous pilonidal or anorectal surgery; immunodeficiency or use of immunosuppressive drugs; insufficient data or loss to follow-up; unwillingness to continue participation.

**Intervention groups**

Intervention group: patients undergoing pilonidal sinus excision with off-midline flap repair. Control group: patients who underwent excision with simple primary closure between 1400 and 1404 (historical control). A single surgeon performs all operations using the same technique, antibiotic regimen and wound care.

**Main outcome variables**

Surgical site infection (CDC criteria); wound dehiscence; subcutaneous fluid collection (seroma or hematoma) within 30 days after surgery.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230409057864N3**
Registration date: **2026-10-22, 1405/07/30**
Registration timing: **prospective**

Last update: **2026-10-22, 1405/07/30**
Update count: **0**

**Registration date**

2026-10-22, 1405/07/30

**Registrant information**

**Name**

ALI MADADI MAHANI

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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madadimahaniali@gmail.com

**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-10-23, 1405/08/01

**Expected recruitment end date**

2027-09-22, 1406/06/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Comparison of Complication Rates Following Pilonidal Sinus Excision with Off-Midline Flap Repair Versus Simple Excision and Primary Closure: A Non-Randomized Quasi-Experimental Study with Historical Controls in Afzalipour and Shahid Bahonar Hospitals, Kerman

**Public title**
Comparing complications of two surgical methods for treating pilonidal sinus
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age 14 to 50 years; Candidate for first-time surgery for pilonidal sinus disease; Signed written informed consent and willingness to attend 6-month follow-up visits
**Exclusion criteria:**
**Age**
From **14 years** old to **50 years** old
**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**
Other
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Afzalipour Hospital, Kerman University of Medical Sciences
**Street address**
Ethics Committee of Afzalipour Hospital, Kerman University of Medical Sciences
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913555
**Approval date**
2026-10-05, 1405/07/13
**Ethics committee reference number**
IR.KMU.AH.REC.1405.112

## Health conditions studied

### 1

**Description of health condition studied**
Pilonidal sinus disease
**ICD-10 code**
L05.9
**ICD-10 code description**
Pilonidal cyst without abscess

## Primary outcomes

### 1

**Description**
Surgical site infection
**Timepoint**
First postoperative days and 30 days after surgery
**Method of measurement**
Clinical examination by the surgeon based on CDC criteria (redness, discharge, or clinically evident infection requiring antibiotic therapy)

### 2

**Description**
Wound dehiscence
**Timepoint**
First postoperative days and 30 days after surgery
**Method of measurement**
Clinical examination by the surgeon (complete or partial separation of wound edges)

### 3

**Description**
Subcutaneous fluid collection (seroma or hematoma)
**Timepoint**
First postoperative days and 30 days after surgery
**Method of measurement**
Clinical examination by the surgeon, confirmed by ultrasonography if needed

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
InterventioIntervention group: patients aged 14–50 years with pilonidal sinus disease who undergo excision with off-midline flap repair. All operations are performed by a

single surgeon using a standardized technique, with standard antibiotic prophylaxis and wound care. Drains are removed based on clinical criteria. Patients are followed up in the first postoperative days and at 30 days, 3 months and 6 months.n group:

**Category**

Treatment - Surgery

**2**

**Description**

Control group: patients aged 14–50 years with pilonidal sinus disease who underwent excision with simple primary closure between 1400 and 1404 at Afzalipour and Shahid Bahonar hospitals (historical control). Surgery was performed according to the standard protocols of these centers. Data on complications and outcomes are extracted from medical records and clinic follow-up notes using a standardized checklist.

**Category**

Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Afzalipour Hospital

**Full name of responsible person**

Dr. Abouzar Pourrashidi

**Street address**

Afzalipour Hospital, Imam Khomeini Highway, Kerman, Iran

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**2**

**Recruitment center**

**Name of recruitment center**

Shahid Bahonar Hospital

**Full name of responsible person**

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

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**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?**

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Abouzar Pourrashidi

**Position**

Assistant Professor of General Surgery

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

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Kerman University of Medical Sciences
**Full name of responsible person**
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**Position**
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**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
To protect participant confidentiality, as stated in the informed consent and approved by the ethics committee, individual participant data will not be shared. The results will be published as aggregated data in scientific journals.
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available