

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison between the complication of Z-plasty repair vs secondary healing in pilonidal sinus.

Protocol summary

Study aim

Comparison of complications between open surgical procedure and Z- plasty in pilonidal sinus surgery

Design

A total of 50 patients, 15 to 40 years old, with Pilonidal sinus, who will refer to the hospital, will be randomly selected and divided into two groups using the Balanced Block Randomization method.

Settings and conduct

After obtaining the necessary permissions from Birjand University of Medical Sciences, 50 patients from the pilonidal sinus that are referred to Imam Reza Hospital will be available in accessible form.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with pilonidal sinus; 20-50 years old. Exclusion criteria: systemic disorders such as diabetes mellitus or other diseases affecting wound healing; Inflammation, infection, discharge : history of corticosteroid use; chemotherapy and other drugs that disrupt the wound healing process; BMI>30; The extent of the ulcer more than 10% of the pilonidal standard size (18 cm²)

Intervention groups

Patients with pilonidal sinus: one group will be treated by open-ended method and the other group by Z-plasty.

Main outcome variables

Recurrence Wound infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111211008375N16**

Registration date: **2018-06-01, 1397/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-01, 1397/03/11**

Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Seyed Amirkazem Vejdani

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3222 2300

Email address

vejdani_sa@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the complication of Z-plasty repair vs secondary healing in pilonidal sinus.

Public title

Comparison between the complication of Z-plasty repair Vs Secondary healing in pilonidal sinus.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with pilonidal sinus

Exclusion criteria:
General disorders, such as diabetes mellitus, or other diseases affecting wound healing : Inflammation, infection, discharge : History of corticosteroid use, chemotherapy and other drugs that disrupt the wound healing process; The extent of each wound is more than 10% of the pilonidal standard size; BMI>30

Age
From **15 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Balanced Block Randomization

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

Ethical committee of Birjand University of Medical Science

Street address

Ghaffari St

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2017-05-06, 1396/02/16

Ethics committee reference number

Ir.bums.REC.1395.265

Health conditions studied

1

Description of health condition studied

Pilonidal sinus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Recurrence

Timepoint

Second and third week and third and sixth months after surgery

Method of measurement

Examination by surgeon

2

Description

Wound infection

Timepoint

Second and third week and third and sixth months after surgery

Method of measurement

Examination by surgeon

Secondary outcomes

empty

Intervention groups

1

Description

Primary repair by Z-plasty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Seyyed AmirKazem Vejdani

Street address

Taleghani St

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9714811151

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemy

Street address

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drtooba.kazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Birjand University of Medical sciences

Position

General surgeon, Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Amir Kazem Vejdan

Position

Specialist in general surgery, Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Toktam Shadi- Sajede Afroozi

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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9715711396

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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

It is a single blinded and the patients' confidentiality concerned

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

Undecided - It is not yet known if there will be 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

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