Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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
Incusion criteria:Patients with pylonidal 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 Vejdan
Name of organization / entity
Birjand University of Medical Sciences
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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 ؛ Inflamation, 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 pylonidal 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 Sciencee

Street address

Ghaffari St

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

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 Vejdan

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Sponsors / Funding sources

1

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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
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
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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