Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Healing by primary closure versus open healing after surgery for pilonidal sinus

Protocol summary

Summary

According to high prevalence of pilonidal sinus and its painful nature which leads to significant morbidity, the pilonidal disease leads to long-lasting disturbance of daily activity. In the view of there is not yet any preferred method (open or closed) in the treatment of pilonidal disease, this study was conducted to compare these two methods. This study is a randomized clinical trial and all patients will be admitted with a diagnosis of pilonidal sinus disease and an informed consent will be taken. Patients randomly assign to either primary closure or secondary healing group. Total sample size was calculated 37cases for each groups of study. In primary repair group, the sinuses, tract and cyst will be removed with a healthy tissue margin of 2-3 mm and the defect will be replaced with a flap method and repaired with nylon string. In addition, a drain will be placed under the flap and will be removed within 24 to 48 hours. In secondary healing group (open group) involved tissues in pilonidal sinus site will be respected and tissue defect will be managed by continuous washing up to closure of wound by secondary healing. In both groups patients will be visited repeatedly the day after surgery, one week, one month and 6 month after surgery and will be evaluated for length of hospital stay, days to work, complete healing time, wound infection and recurrence of disease. All data will be recorded and statistically analyzed. In all cases, P value less or equal to the 0.05 will be considered statistically significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031312801N1**
Registration date: **2013-07-17, 1392/04/26**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-07-17, 1392/04/26

Registrant information

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Name of organization / entity
Hamedan University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Hamedan Univesity of Medical Sciences

Expected recruitment start date

2013-01-04, 1391/10/15

Expected recruitment end date

2013-07-06, 1392/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Healing by primary closure versus open healing after surgery for pilonidal sinus

Public title

Healing by primary closure versus open healing after surgery for pilonidal sinus

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criterion: patients referred to general surgery clinic with pidonidal disease. Exclusion criteria: chronic underlying disease; active infection at pilonial sinus site; patients with pilonidal abcess which were candidate to urgent drainage.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamedan Univesity of medical sciece
Street address
Hamedan, Hamedan University of Medical Science, Medicine university.
City
Hamedan
Postal code
Approval date
2013-01-01, 1391/10/12
Ethics committee reference number
16/35/9/3492/د/پ

Health conditions studied

1

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

Primary outcomes

1

Description
infection of wound site
Timepoint
1st day, 1st week, 1st month, 6th month.
Method of measurement
physical examination and history

2

Description
recurrance of disease
Timepoint
1st month, 6th month.
Method of measurement
physical examination

3

Description
time of complete healing of wound
Timepoint
1st week, 1st month, 6th month
Method of measurement
physical examination and history

4

Description
day to work
Timepoint
1st day. 1st week, 1st month, 6th month.
Method of measurement
history

Secondary outcomes

1

Description
length of stay at hospital
Timepoint
at time of admission and discharge
Method of measurement
following of admission

Intervention groups

1

Description
Surgery methods in control group: excision of affected tissue and secondary healing.
Category
Treatment - Surgery

2

Description

Surgery method in intervension group: excision of affected tissue and repair of wound with flap method.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Makarchian

Street address

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Science research deputy

Full name of responsible person

Dr. Mohamad Hazavei

Street address

Hamedan University of Medical Science, Shahid Fahmide st.

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Science research deputy

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical science

Full name of responsible person

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Position

general surgery resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty