

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Name

Hamid Reza Makarchian

Name of organization / entity

Hamedan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0078

Email address

hr.makarchian@umsha.ac.ir

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 pilonidal disease. Exclusion criteria: chronic underlying disease; active infection at pilonidal sinus site; patients with pilonidal abscess 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 University of medical science

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

recurrence 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 intervention 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