

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of primary closure, secondary closure (open) and Limberg flap for the treatment of pilonidal Sinus

Protocol summary

Study aim

The aim of current study is to compare the treatment of pilonidal sinus with primary, secondary (open) and Limberg flap on treatment outcome and complications rate.

Design

In this clinical trial, 150 patients with pilonidal sinus will be randomly assigned to three 50 patients groups of treatment with primary methodm Limberg flap and secondary method.

Settings and conduct

Patients with pilonidal sinusvisiting Sina Hospital, Tabriz were treated after randomly allocation to three groups. Patients and the person evaluating the outcome were blinded to the allocation group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patterns with primary pilonidal sinus; exclusion criteria: recurrent pilonidal sinus, pilonidal abcess, diabetes mellitus

Intervention groups

First group will be treated with primary method, second group with Limberg flap and third group with secondary method.

Main outcome variables

Patients will be evaluated for recurrence and complications and improvement rate after one week, one months and three months post surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180606039985N1**

Registration date: **2018-09-17, 1397/06/26**

Registration timing: **retrospective**

Last update: **2018-09-17, 1397/06/26**

Update count: **0**

Registration date

2018-09-17, 1397/06/26

Registrant information

Name

Hemmat Maghsoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-04-03, 1396/01/14

Actual recruitment end date

2018-03-14, 1396/12/23

Trial completion date

2018-08-16, 1397/05/25

Scientific title

Comparison of primary closure, secondary closure (open) and Limberg flap for the treatment of pilonidal Sinus

Public title

Comparison of different closure methods for the treatment of pilonidal Sinus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with primary pilonidal sinus

Exclusion criteria:

Patients with relapse of pilonidal sinus patients with pilonidal abscess patients with diabetes mellitus

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly divided by using a computer-generated random number list. The subjects are assigned into different groups by random allocation. Allocation concealment is obtained by maintaining the randomization list by study statistician.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person evaluating the outcome will be blinded to the allocated group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht Ave.,

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Tabriz

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East Azarbaijan

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5166615556

Approval date

2018-04-10, 1397/01/21

Ethics committee reference number

IR.TBZMED.REC.1397.010

Health conditions studied**1****Description of health condition studied**

Pilonidal sinus

ICD-10 code

L05

ICD-10 code description

Pilonidal cyst and sinus

Primary outcomes**1****Description**

Pilonidal sinus recurrence

Timepoint

One week, one month and 3 months after surgery

Method of measurement

With physical examination

2**Description**

Wound infection

Timepoint

One week, one month and 3 months after surgery

Method of measurement

With Physical examination

Secondary outcomes**1****Description**

Complications

Timepoint

One week, one month and 3 months after surgery

Method of measurement

With physical examination

Intervention groups**1****Description**

First group will undergo treatment of pilonidal sinus with primary method by two crescentic incisions and the cyst will be removed and then sutured .

Category

Treatment - Surgery

2**Description**

Second group will undergo treatment of pilonidal sinus with Limberg flap metho with rhomboid incision, cyst removal, suture and hemovac insretion.

Category

Treatment - Surgery

3

Description

Third group will undergo treatment of pilonidal sinus with secondary method by two crescentic incisions and the cyst will be removed but the cut is not closed

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Hemmat Maghsoudi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Vice-Chancellor of research, Tabriz University of Medical Sciences

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hemmat Maghsoudi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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

Yes - There is 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

Not applicable

Title and more details about the data/document

We have not yet set a conclusion

When the data will become available and for how long

We have not yet set a conclusion

To whom data/document is available

We have not yet set a conclusion

Under which criteria data/document could be used

We have not yet set a conclusion

From where data/document is obtainable

We have not yet set a conclusion

What processes are involved for a request to access data/document

We have not yet set a conclusion

Comments