Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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
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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 abcess 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.,

City
Tabriz

Province
East Azarbaijan

Postal code
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 Maghsudi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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
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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