Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method

Protocol summary

Study aim
Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method

Design
In this double-blind clinical trial study (participants and results analyzer), patients will undergo surgery after random allocation in the two mentioned groups. For one group, the routine procedure will be performed and for the other group, Hook's circulators will be performed minimally invasively, and the results after surgery will be compared between the two groups.

Settings and conduct
This study is a randomized clinical trial (blocks of four), double blind (participants and results analyzer), with parallel groups, without a control group and with the participation of 80 patients with pilonidal sinus surgery referred to Imam Reza Hospital (Tabriz).

Participants/Inclusion and exclusion criteria
The inclusion criteria include: age over 18 years, consent to participate in the study and suffering from pilonidal sinus will be determined by the doctor, and the exclusion criteria will also include: history of uncontrolled blood pressure and recurrent pilonidal sinus.

Intervention groups
In this study, patients who will refer to the operating room due to pilonidal sinus surgery will undergo intervention. Patients will be randomly divided into two groups. For one group, the routine procedure will be performed and for the other group, Hook's circulators will be performed minimally invasively, and the results after surgery will be compared between the two groups.

Main outcome variables
Infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043107N43**
Registration date: **2024-02-10, 1402/11/21**
Registration timing: **prospective**

Last update: **2024-02-10, 1402/11/21**
Update count: **0**

Registration date
2024-02-10, 1402/11/21

Registrant information

Name
Mehdi Khanbabayi Gol

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 7054

Email address
khanbabayimehdi69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-14, 1402/12/24

Expected recruitment end date
2025-03-14, 1403/12/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method

Public title
Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Consent to participate in the study Having pilonidal sinus as diagnosed by a specialist doctor
Exclusion criteria:
History of uncontrolled blood pressure Recurrent pilonidal sinus
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they will divid into two intervention groups (group A) and control group (group B).
Blinding (investigator's opinion)
Double blinded
Blinding description
The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner. Since the participants will be unaware of the type of technique used, in this study they will not know what type of technique will be used in other patients.
Placebo
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
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5165665631
Approval date
2023-12-17, 1402/09/26
Ethics committee reference number
IR.TBZMED.REC.1402.708

Health conditions studied

1

Description of health condition studied
Infection
ICD-10 code
A04
ICD-10 code description
Other bacterial intestinal infections

Primary outcomes

1

Description
Infection
Timepoint
Once a week in the first thirty days after surgery
Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The surgical procedure will be as follows: using hook circulators under the video guide, the pitting area of the pilonidal sinus is removed in a circular manner and entered into the sinus cavity, then electrical curettage is performed using hook circulators instead of mechanical curettage. Finally, the infection rate will be

measured.

Category

Treatment - Devices

2

Description

Control group: The surgical procedure will be as follows, without using hook circulators, under the video guide, the pitting area of the pilonidal sinus is removed in a circular manner and entered into the sinus cavity, then electrical curettage is performed using hook circulators instead of mechanical curettage. Finally, the infection rate will be measured.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Ramin Azhoogh

Street address
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan

Postal code
6165665631

Phone
+98 21 3335 5921

Email
mkhanbabayi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

Street address
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Phone
+98 41 3335 7310

Email
Ajouyban@hotmail.com

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
Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5981764863

Phone
+98 41 3334 7054

Fax

Email
Khanbabayimehdi69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan
Postal code
5981764863
Phone
+98 41 3334 7054
Fax
Email
Khanbabayimehdi69@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863
Phone
+98 41 3334 7054
Fax
Email
Khanbabayimehdi69@gmail.com

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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable