

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 analyst

## 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 divide 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

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Imam Reza Hospital, Azadi Ave

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolghasem Jouyban

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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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**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

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Imam Reza Hospital, Azadi Ave

**City**

Tabriz

**Province****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