

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of the results and complications of phenol injection in the treatment of patients with simple pilonidal sinus referred to Imam Khomeini Hospital in ۲۰۲۳

#### Protocol summary

##### Study aim

Treatment of pilonidal sinus disease with fewer complications and a shorter recovery period

##### Design

A semi-experimental trial with one intervention group, on 20 patients, phase 3

##### Settings and conduct

Patients with mild form of pilonidal sinus referred to Imam Khomeini Hospital in 2023 will be included in the study. after local anesthesia, the skin will be prepared . First, curettage and then phenol crystal injection will be done, and after the sinus contents are removed, washing and dressing will be done. All patients will be followed up by phone call or visiting the clinic in person. Cases of pain, need for analgesia, discharge, infection and other complications, and duration of rest and time to return to normal activity will be recorded.

##### Participants/Inclusion and exclusion criteria

Patients with a mild form of pilonidal sinus (no lateral extension, no previous history of surgical treatment, no abscess)

##### Intervention groups

Intervention group: Use of phenol crystal

##### Main outcome variables

Pain; Need to receive painkillers, discharge or infection, time to return to normal life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230602058367N1**

Registration date: **2023-09-15, 1402/06/24**

Registration timing: **prospective**

Last update: **2023-09-15, 1402/06/24**

Update count: **0**

##### Registration date

2023-09-15, 1402/06/24

##### Registrant information

###### Name

Mohammad Javad SheykhAboli

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2112

###### Email address

mjavadsh14@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2023-12-30, 1402/10/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the results and complications of phenol injection in the treatment of patients with simple pilonidal sinus referred to Imam Khomeini Hospital in ۲۰۲۳

##### Public title

results and complications of phenol injection in the treatment of patients with simple pilonidal sinus

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
patients with a simple form of pilonidal sinus (only having a secretory pit in the mid- line) No previous history of surgical treatment

**Exclusion criteria:**  
The presence of lateral extention (secretion pit on the outside of the midline). presence of abscess

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: 20

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Tehran University of Medical Sciences

**Street address**  
Dr. Gharib Street- At the end of Keshavarz Boulevard

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
۱۴۱۹۷۳۳۱۴۱

**Approval date**  
2022-10-18, 1401/07/26

**Ethics committee reference number**  
IR.TUMS.IKHC.REC.1401.357

## Health conditions studied

### 1

**Description of health condition studied**

Pilonidal sinus

**ICD-10 code**  
L05.92

**ICD-10 code description**  
Pilonidal sinus without abscess

## Primary outcomes

### 1

**Description**  
pain,

**Timepoint**  
Periods of 1, 2, 3, 6, 9 and 12 months

**Method of measurement**  
Call or visit the clinic in person

### 2

**Description**  
need to take painkillers

**Timepoint**  
Periods of 1, 2, 3, 6, 9 and 12 months

**Method of measurement**  
Call or visit the clinic in person

### 3

**Description**  
discharge or infection

**Timepoint**  
Periods of 1, 2, 3, 6, 9 and 12 months

**Method of measurement**  
Call or visit the clinic in person

### 4

**Description**  
Rest period and time to return to normal activity

**Timepoint**  
Periods of 1, 2, 3, 6, 9 and 12 months

**Method of measurement**  
Call or visit the clinic in person

## Secondary outcomes

### 1

**Description**  
need to take painkillers

**Timepoint**  
Periods of 1, 2, 3, 6, 9 and 12 months

**Method of measurement**  
Call or visit the clinic in person

## Intervention groups

### 1

**Description**  
Among the patients with pilonidal sinus disease referred in 2023, people with a simple form of pilonidal sinus

(with only a hole in the midline), without previous history of surgical treatment, will be selected as the inclusion criteria for the study. If there is a lateral extension (secreting hole on the outside of the midline) and an abscess, the patient will be excluded from the study (exclusion criteria). Among the selected people, different treatment methods will be explained. The advantages and disadvantages of using phenol will be explained, and if they are satisfied, the candidate will be treated with phenol crystal and will be included in the study. The required phenol crystal is provided through the Faculty of Pharmacy. After entering the study, on the day of surgery and after admitting the patient to the operating room, the patient lies in the prone position on the bed of the operating room. After exposing the surgical site and disinfecting the site with betadine (prep) and dropping them (drape), xylocaine/lidocaine anesthetic is injected. After obtaining the desired anesthesia, the surrounding area is lubricated with silver sulfadiazine or zinc oxide ointment (to protect the skin), probing is performed through the existing holes. After obtaining the size of the sinus by measuring the tip of the probe, the inside of the sinus is physically deepened by a curette and the material inside the sinus is removed. Then the phenol crystal will enter the sinus (the crystal will melt after contact with the body due to heat). After the effect of phenol, secretions and debris inside the sinuses will be removed. After finishing the work and cleaning the position, sterile dressing will be done.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Mohammad Javad Sheikh Aboli

##### Street address

Dr. Gharib Street At - the end of Keshavarz Boulevard

##### City

Tehran

##### Province

Tehran

##### Postal code

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##### Phone

+98 21 6119 2112

##### Email

mjavadsh14@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Akbar Fotuhi

#### Street address

Research and Technology Vice-Chancellor, Central Organization of the University 6th floor, corner of Quds St, Keshavarz Blvd

#### City

tehran

#### Province

Tehran

#### Postal code

1419733141

#### Phone

+98 21 8163 3685

#### Email

vcr@sina.tums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Research and Technology Vice-Chancellor

#### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Javad Sheikh Aboli

##### Position

General surgery residen

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Surgery

##### Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6119 2112

##### Email

mjavadsh14@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Amir Keshvari

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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Tehran, Iran

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**Phone**

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**Email**

keshvari@tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Javad SheykhAboli

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Central Pavilion, Imam Khomeini Hospital Complex;  
South Side, Imam Khomeini Hospital Complex South

Side, End of Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 2112

**Fax****Email**

mjavadsh14@gmail.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The result of the study

**When the data will become available and for how long**

After publication

**To whom data/document is available**

Students and faculty

**Under which criteria data/document could be used**

Conduct additional research

**From where data/document is obtainable**

executor of plan

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

Email

**Comments**