Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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)

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+98 21 6119 2112

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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

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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

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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
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Position
General surgery residen

Latest degree
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Other areas of specialty/work
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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