Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

The effect of phenol on recurrent pilonidal sinus in 1404 (uncontrolled studies)

Protocol summary

Study aim
The effect of phenol on recurrent pilonidal sinus in 1404 (uncontrolled studies)

Design
Clinical trial without control group, with only one group, Phase 2 on 31 patients. SPSS program (version 22.0) will be used in the analyses.

Settings and conduct
Patients who refer to the General Surgery Clinic of Mazandaran University of Medicine and Imam Sari Hospital for their pineal sinus recurrence. After local anesthesia is performed around the holes, a mosquito clamp will be placed inside the sinus, the hair will be removed, and the skin around the hole will be covered with nitrofurantoin ointment (Furacin, Eczacıbaşı İlaç San. ve Tic. AŞ, İstanbul, Turkey.) to prevent chemical irritation. Then, crystallized phenol will be inserted into the sinus with the same clamp. When an abscess is diagnosed, the abscess will be drained first and CPT will be performed at the same time. Patients will be allowed to return to their daily activities after this procedure. This procedure will be performed every three weeks. If there is discharge from the wound during the follow-up examination, this procedure will be repeated. Closure of the sinus hole and complete disappearance of discharge will be considered as recovery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People who presented with recurrent pineal sinus. Exclusion criteria: Unwillingness to participate in the study and those with incomplete information. In addition, those who did not come to their usual follow-up visits or could not be contacted were not included in the study. And people with diabetes

Intervention groups
2-5 grams of crystallized phenol

Main outcome variables
Reducing pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130826014483N13**
Registration date: **2025-08-05, 1404/05/14**
Registration timing: **prospective**

Last update: **2025-08-05, 1404/05/14**
Update count: **0**

Registration date
2025-08-05, 1404/05/14

Registrant information

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Mina Alvandipour
Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-10, 1404/05/19

Expected recruitment end date
2025-10-11, 1404/07/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of phenol on recurrent pilonidal sinus in 1404 (uncontrolled studies)

Public title
The effect of phenol on recurrent pilonidal sinus in 1404 (uncontrolled studies)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People who present with recurrent pilonidal sinus
Exclusion criteria:
Unwillingness to participate in the study Those with incomplete information, as well as those who did not attend their regular follow-up visits or could not be contacted, were not included in the study. People who have diabetes

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **31**

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
Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran
Street address
Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran
City
Sari
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Mazandaran
Postal code
33131 - 48166

Approval date
2025-07-20, 1404/04/29

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1404.033

Health conditions studied

1

Description of health condition studied
Pilonidal cyst and sinus

ICD-10 code
L05

ICD-10 code description
Pilonidal cyst and sinus

Primary outcomes

1

Description
Reducing pain

Timepoint
1, 5, 7 days after using the medicine

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Pilonidal sinus recurrence rate

Timepoint
2 weeks after and 1 month after injection

Method of measurement
Clinical examination

2

Description
Itching

Timepoint
Days 3, 1, 5, 1 week later, 1 month later

Method of measurement
Clinical examination

3

Description
Burn

Timepoint
Days 3, 1, 5, 1 week later, 1 month later

Method of measurement
Clinical examination

4

Description
Abscess

Timepoint
Days 3, 1, 5, 1 week later, 1 month later

Method of measurement

Clinical examination

Intervention groups

1

Description
Intervention group:2-5 grams of crystallized phenol, made in Germany, is filled into the sinus with the help of a clamp, dissolves quickly at body temperature, excess phenol is removed from the sinus and carefully removed from the area. The duration of phenol's presence in the sinus tract is an important factor for the success of the treatment. The duration of phenol's presence in the sinus will be about 2-8 minutes.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran

Full name of responsible person
Mina Alvandipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Ahmadali Enayati

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Research and Technology Center, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran

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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Mina Alvandipour

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available