

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the effect of preoperative epinephrine injection on bleeding after oxidation of palynodinal sinus with the control group in patients referring to Ayatollah Taleghani hospital of Kermanshah

Protocol summary

Study aim

Comparison of the effect of preoperative epinephrine injection on bleeding after oxidation of pilonidal sinus with the control group in patients referring to Ayatollah Taleghani hospital of Kermanshah

Design

This study is one-blinded clinical trial. The study population will be included all patients with pilonidal sinus referred to Taleghani hospital of Kermanshah. 100 eligible patients will be selected conveniently and randomly will be assigned into intervention and control groups.

Settings and conduct

This study which will be conducted in Taleghani hospital of Kermanshah city is one-blinded one, that the participants will not know which group they will be assigned

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who undergo Pilonidal sinus surgery for the first time. Be at least 14 years of age.
Exclusion criteria: Patients with ischemic heart disease, diabetes, hypertension, renal failure, acute infection and abscess; small size of the sinus

Intervention groups

In the intervention group, 3 CC epinephrine with a concentration of 1 / 10,000,000 is injected subcutaneously before surgery. In the control group, 3 cc of normal saline is injected and after 15 minutes surgery will begin.

Main outcome variables

Amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N121**

Registration date: **2019-05-19, 1398/02/29**

Registration timing: **prospective**

Last update: **2019-05-19, 1398/02/29**

Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of preoperative epinephrine injection on bleeding after oxidation of pilonidal sinus

with the control group in patients referring to Ayatollah Taleghani hospital of Kermanshah

Public title

The effect of epinephrine injection on bleeding after oxidation of palynodinal sinus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who undergo Pilonidal sinus surgery for the first time Be at least 14 years of age

Exclusion criteria:

Patients with ischemic heart disease, diabetes, hypertension, renal failure, acute infection and abscess small size of the sinus

Age

From **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization using a random number table via code receipt

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the participant will kept blinded to the allocation of study groups to the intervention and control groups, the dosage of the drug and the manufacturer of the medicine. In this way, the participants will be unaware of how the participants will be coded and how much drug they will received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid

Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-04-24, 1398/02/04

Ethics committee reference number

ir.kums.rec.1398.108

Health conditions studied

1

Description of health condition studied

Pilonidal sinus

ICD-10 code

L05

ICD-10 code description

Pilonidal cyst and sinus

Primary outcomes

1

Description

Amount of bleeding

Timepoint

Immediately after surgery

Method of measurement

Based on the number of gauze bandages that are completely soaked

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, 3 CC epinephrine with a concentration of 1 / 10,000,000 is injected subcutaneously before surgery.

Category

Treatment - Drugs

2

Description

In the control group, 3 cc of normal saline is injected and after 15 minutes surgery will begin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Mehran Norozi

Street address

Shahid Beheshti Blvd., Taleghani Hospital

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Province

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Postal code

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Phone

+98 83 3837 0139

Email

Www.mehrannoroozi813@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mehtan Norozi

Position

Resident of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Arash Koohi

Position

Member of the faculty of Kermanshah University of
Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mehran Norozi

Position

Resident of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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

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

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 40-day period, the documents will be sent e-mail

Comments