Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 papelonidinal 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 Keranshah 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 Pelonidal 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)

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+98 83 1821 4653

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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 palynodinal 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 Pelonidal 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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Email
Www.mehrannowroozi813@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Farid Najafi

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

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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

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Dr. Arash Koohi

Position
Member of the faculty of Kermanshah University of Medical Sciences

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Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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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