

# 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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847167

**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  
Beheshti

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fnajafi@kums.ac.ir

**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**

Shahid Beheshti Blvd Taleghani Hospital

**City**

Kermanshah

**Province**

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**Postal code**

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**Phone**

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**Email**

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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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Shahid Beheshti Blvd., Taleghani Hospital

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**Province**

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**Email**

Arash\_koohi\_ar@yahoo.com

## 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

**Street address**

Shahid Beheshti Blvd., Taleghani Hospital

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847167

**Phone**

+98 83 3837 0139

**Email**

Www.mehrannowroozi813@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**

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**