

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Effect of turmeric extract versus topical phenytoin and placebo on healing of open wound after pilonidal sinus surgery: a double blind randomized clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of turmeric extract versus topical phenytoin and placebo on healing of open wound after pilonidal sinus surgery. Design: A double blind randomized clinical trial. Setting and conduct: The eligible patients with pilonidal sinus who will undergo surgery in Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 65 years; pilonidal sinus candidate for surgery. Exclusion criteria: Diabetes; Immunodeficiency; local abscess. Intervention group 1: Topical cream including turmeric extract on surgical wound twice a day for 2 weeks. Intervention group 2: Topical cream including phenytoin on surgical wound twice a day for 2 weeks. Control group: Topical placebo cream on surgical wound twice a day for 2 weeks Primary outcome: Healing of surgical wound one and two week and also one month after surgery via physical examination. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201711129014N200**  
Registration date: **2017-11-14, 1396/08/23**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-11-14, 1396/08/23

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice-chancellor for Research and Technology, Hamadan  
University of Medical Sciences

#### Expected recruitment start date

2017-11-21, 1396/08/30

#### Expected recruitment end date

2018-01-20, 1396/10/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of turmeric extract versus topical phenytoin and placebo on healing of open wound after pilonidal sinus surgery: a double blind randomized clinical trial

#### Public title

Effect of turmeric extract versus topical phenytoin and placebo on healing of open wound after pilonidal sinus surgery

#### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Age of 18 to 65 years; pilonidal sinus candidate for surgery. Exclusion criteria: Diabetes; Immunodeficiency; local abscess.

### **Age**

From **18 years** old to **65 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **63**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

##### **Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### **City**

Hamadan

##### **Postal code**

#### **Approval date**

2017-10-14, 1396/07/22

#### **Ethics committee reference number**

IR.UMSHA.REC.1396.495

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Pilonidal sinus

#### **ICD-10 code**

L05

#### **ICD-10 code description**

Pilonidal cyst

## **Primary outcomes**

### **1**

#### **Description**

Healing of surgical wound

#### **Timepoint**

one and two week and also one month after surgery

#### **Method of measurement**

Via physical examination

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: Topical cream including turmeric extract on surgical wound twice a day for 2 weeks.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group 2: Topical cream including phenytoin on surgical wound twice a day for 2 weeks.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Control group: Topical placebo cream on surgical wound twice a day for 2 weeks

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Besat Hospital

##### **Full name of responsible person**

Dr Nayereh Erfani Moghaddam

##### **Street address**

Besat Hospital, Shahed Square

##### **City**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for Research and Technology, Hamadan  
University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Besat Hospital

**Full name of responsible person**

Dr Nayereh Erfani Moghaddam

**Position**

Resident of Surgery

**Other areas of specialty/work****Street address**

Besat Hospital, Shahed Square

**City**

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+98 81 3364 0030

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n85erf@gmail.com

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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

Besat Hospital

**Full name of responsible person**

Dr Seyyed Mohammad Reza Javadi

**Position**

Surgeon

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Besat Hospital, Shahed Square

**City**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Other areas of specialty/work****Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*