

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparing the anesthetic effect of topical amitriptyline jell 2% versus topical lidocaine jell 2% in patients with isolated limb wounds needing primary repair with suture: a randomized clinical trial

#### Protocol summary

##### Study aim

To compare the anesthetic effect of topical amitriptyline jell 2% versus topical lidocaine jell 2% in patients with isolated limb wounds needing primary repair with suture

##### Design

This a randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients with isolated limb wounds needing primary repair with suture who will refer to Besat Hospital during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60 years Having isolated limb wounds needing primary repair with suture  
Exclusion criteria: Using monoamine oxidase inhibitors Cardiovascular diseases Arterial active bleeding Unstable vital signs

##### Intervention groups

Intervention group: Topical amitriptyline 2% with the amount of 2 mg/kg single dose Control group: Topical lidocaine 2% with the amount of 2 mg/kg single dose

##### Main outcome variables

Primary outcome: Assessing the pain before suture and at 1, 3, 5, 7, and 9 minutes after suture using VAS

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N216**  
Registration date: **2018-03-20, 1396/12/29**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-20, 1396/12/29**

Update count: **0**

##### Registration date

2018-03-20, 1396/12/29

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-11, 1396/12/20

##### Expected recruitment end date

2018-09-22, 1397/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the anesthetic effect of topical amitriptyline jell 2% versus topical lidocaine jell 2% in patients with isolated limb wounds needing primary repair with suture: a randomized clinical trial

##### Public title

Comparing the anesthetic effect of topical amitriptyline

jell 2% versus topical lidocaine jell 2% in patients with isolated limb wounds needing primary repair with suture

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Age of 18 to 60 years Having isolated limb wounds needing primary repair with suture

#### **Exclusion criteria:**

Using monoamine oxidase inhibitors Cardiovascular diseases Arterial active bleeding Unstable vital signs

### **Age**

From **18 years** old to **60 years** old

### **Gender**

Both

### **Phase**

2

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

*No information*

### **Sample size**

Target sample size: **90**

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

Randomized

### **Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization

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

Not blinded

### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

### **Other design features**

## **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**

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##### **Province**

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##### **Postal code**

6517838695

#### **Approval date**

2018-02-24, 1396/12/05

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

IR.UMSHA.REC.1396.811

## **Health conditions studied**

### 1

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

Isolated limb wounds

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

S81

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

Open wound of knee and lower leg

## **Primary outcomes**

### 1

#### **Description**

Assessing the pain

#### **Timepoint**

Before suture and at 1, 3, 5, 7, and 9 minutes after suture

#### **Method of measurement**

Using VAS

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Topical amitriptyline 2% with amount of 2 mg/kg single dose

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Topical lidocaine 2% with amount of 2 mg/kg single dose

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Besat Hospital

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

Dr Farnoosh Jalilvand

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
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info.research@umsha.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Hamedan 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**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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## Person responsible for scientific inquiries

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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