

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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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
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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

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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
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
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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