

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the effect of prioperative intravenous lidocaine infusion on post operative pain and analgesic requirement in tibial fracture surgery

Protocol summary

Summary

The purpose of this study is evaluating of analgesic effect of preemptive lidocain infusion on postoperative pain and opioid consumption after tibial fracture surgery. 48 patients participated in this randomized double-blinded study . patients were grouped as lidocain and control group. 24 Patients received lidocaine (lidocaine group) with a 1.5 mg/kg intravenous bolus and followed by a 1.5 mg / kg / hrs intravenous infusion And 24 patients received saline(control group). Visual analog scale (VAS) scores at 1 -2-4-12 -16 -20-24, the time to first analgesic requirement ,total analgesic consumption in first 24hrs and side effect were noted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104306337N1**

Registration date: **2011-09-22, 1390/06/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-22, 1390/06/31

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2010-10-12, 1389/07/20

Expected recruitment end date

2011-06-11, 1390/03/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of prioperative intravenous lidocaine infusion on post operative pain and analgesic requirement in tibial fracture surgery

Public title

Evaluation of the effect of prioperative intravenous lidocaine infusion on post operative pain and analgesic requirement in tibial fracture surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patients undergoing tibial fracture surgery under general anesthesia; age 18-50inclusive; ASA class I patients ; Body Mass Index (BMI) of 18.5-35 (Includes 18.5 to 25 – healthy range; >25-30 overweight; >30-35 Obese Class I); Exclusion Criteria: patients under age 18 or over age50; ASA,II III, IV and V class patients ; Obese Class II patients (BMI>35) or undernourished (BMI<18.5); history of Liver dysfunction ; renal insufficiency; history of seizure disorder; hypersensitivity or allergy to amide type local anesthetics; medication use(daily use of any opioids or analgesic) and any chronic pain syndromes ;

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapour university of medical sciences

Street address

Shaher daneshgah

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Postal code

6135715794

Approval date

2010-10-09, 1389/07/17

Ethics committee reference number

ETH009

Health conditions studied

1

Description of health condition studied

Pain relief after tibial fracture surgery

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Pethedine consupsion

Timepoint

1, 2, 4, 12 , 16 , 20 and 24 hours post extubation

Method of measurement

Medical records

Secondary outcomes

1

Description

Pain

Timepoint

1, 2, 4, 12 , 16 , 20 and 24 hours after extubation

Method of measurement

Visual analog scale (VAS)

Intervention groups

1

Description

Patient s in control group received normal saline IV infusion

Category

Placebo

2

Description

Patients in intervention group received lidocaine (lidocaine group) with a 1.5 mg/kg intravenous bolus and followed by a 1.5 mg . kg intravenous infusion

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospitaL

Full name of responsible person

Dr. Sholeh Nesioonpour

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Azadegan St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

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Grant name
129006

Grant code / Reference number
10506

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz Jundishapur 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

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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