Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Name

Vahid Salehi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8307

Email address

salehi.v@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapour 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 opiods 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

City

Ahvaz

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 consumpsion

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

Street address

Azadegan St.

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

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
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Sholeh Nesioonpour
Position
Assistant professor
Other areas of specialty/work
Street address
General operation room, Imam Khomeini hospital
City
Ahvaz
Postal code
6193673166
Phone
+98 61 1222 2114
Fax
+98 61 1222 5763
Email
Dr.nesioun@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Pipelzadeh
Position
Associate professor
Other areas of specialty/work
Street address
Imam khomini Hospital, Azadegan St.
City
AHVAZ
Postal code
6193673166
Phone
+98 61 1222 2114
Fax
+98 61 1222 2114
Email
dr_rpipel@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Vahid Salehi
Position
Anesthesiology Resident
Other areas of specialty/work
Street address
Imam khomini hospital, Azadegan St
City
Ahvaz
Postal code
6193673166
Phone
+98 61 1338 0138
Fax
Email
salehivahid61@yahoo.com
Web page address

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