Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effectiveness of intravenous lidocaine in comparison to morphine sulfate in patients suffering from limb trauma who come to emergency department of Imam Khomeini Hospital between 01.01.2015 and 20.03.2015

Protocol summary

Summary

This is a randomized triple blinded clinical trial and include all patients with inclusion criteria of study who come to ED of Imam Khomeini Hospital.After signing of inform consent and describing of the study for patients, pain level calculate with using NRS then each of them allocated randomize to study groups.First group will treat with 0.1 mg/kg morphine sulfate(Daru Pakhsh CO. Tehran, Iran) via slow venous infusion and second group 1.5 mg/kg lidocaine(Caspian Daru CO, Rasht, Iran). Patients allocated to group A and B by Balanced Block Randomization. After pain level calculation and consistent of significant pain(NRS> 5/10) patients assign to group A or B and receive 0.1 mg/kg morphine sulfate or 1.5 mg/kg Lidocaine via sloe venous infusion. Primary aim is achieving patient satisfaction by decreasing pain level without complication.(NRS< 5) We also consider positive response to treatment if patient show at least 3 score decrement in NRS(the final score must be below 5). We calculate NRS before treatment and 15. 30, 45 and 60 min after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080518698N1**
Registration date: **2015-03-15, 1393/12/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name
Hadid Hamrah
Name of organization / entity
Hadid Hamrah
Country
Iran (Islamic Republic of)
Phone
+98 912 326 5574
Email address
hadid_ham@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-12-31, 1393/10/10

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of intravenous lidocaine in comparison to morphine sulfate in patients suffering from limb trauma who come to emergency department of Imam Khomeini Hospital between 01.01.2015 and 20.03.2015

Public title

Evaluation of effectiveness of intravenous lidocaine in comparison to morphine sulfate in patients suffering from limb trauma

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria : age over 16 & less than 65 years old ; acute upper or lower limb trauma including soft tissue injury ,torsion,dislocation,fractures, as a main cause of arrival in ED (less than 24 hrs from iniatiating of trauma event.) ; need to administer pain reilefer(NRS>5 /pain score over 5) exclusion criteria : altered mental status (glasgow coma scale <15) ; hemodynamic instability (SBP≤90, PR≤60, RR≤8 , 90% ≥ O2) and in patient with hypertention (180 ≤SBP) or (SBP≤100) ; hypersensivity to lidocaein & morphine
Age
From **16 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Education building of Tehran University of Medical Sciences, Quds Street, Keshavarz Blvd, Tehran, Iran
City
Tehran
Postal code
Approval date
2014-12-14, 1393/09/23
Ethics committee reference number
9111307039-129232

Health conditions studied

1

Description of health condition studied
limb pain secondary to trauma
ICD-10 code
T00.6
ICD-10 code description
Superficial injuries involving multiple regions of upper limb(s) with lower limb(s)

Primary outcomes

1

Description
Pain level changing in patients
Timepoint
Every 15 min till one hour
Method of measurement
With Numeric Rating Scale that ask to the patient

Secondary outcomes

1

Description
Time of pain relief in patients recieve lidocaine
Timepoint
Every 15 min till one hour
Method of measurement
With Numeric Rating Scale that ask to the patient

Intervention groups

1

Description
Triple Blinded Randomized Clinical Trial
Category
Treatment - Drugs

2

Description
First group will be treated by 0.1 mg/kg morphine sulfate(Daru Pakhsh CO. Tehran, Iran) via slow venous infusion . We calculate NRS before treatment and 15. 30, 45 and 60 min after treatment.
Category
Treatment - Drugs

3

Description
second group will be treated by 1.5 mg/kg lidocaine(Caspian Daru CO, Rasht, Iran) via slow venous infusion . We calculate NRS before treatment and 15. 30, 45 and 60 min after treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hadid Hamrah
Street address
Imam Khomeini Hospital , Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University Of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh Basti
Street address
No. 1, North door of Tehran University, Poursina street, Enghelab street ,Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University Of Medical Sciences
Full name of responsible person
Hadid Hamrah
Position
Emergency Medicine Resident
Other areas of specialty/work
Street address
Imam Khomeini Hospital, Tehran
City
Tehran
Postal code
Phone
+98 912 326 5574
Fax
Email
hadid_ham@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University Of Medical Sciences
Full name of responsible person
Hadid Hamrah
Position
Emergency Medicine resident
Other areas of specialty/work
Street address
Imam Khomeini Hospital, Tehran
City
Tehran
Postal code
Phone
+98 912 326 5574
Fax
Email
hadid_ham@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hadid Hamrah
Position
Emergency Medicine Resident
Other areas of specialty/work
Street address
Imam Khomeini Hospital , Tehran
City
Tehran
Postal code
Phone
+98 912 326 5574
Fax
Email
hadid.hamrah@gmail.com ; hadid_ham@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