

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 Paksh 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)

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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 initiating of trauma event.) ; need to administer pain reliefer(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 hypertension (180 ≤SBP) or (SBP≤100) ; hypersensitivity to lidocaine & 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 receive 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

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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