

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of Analgesic effect of intravenous lidocaine versus intravenous morphine sulfate in pain reduction in long or short bones fractures of upper and lower limbs

Protocol summary

Summary

Purpose of study: Evaluation of Analgesic effect of intravenous lidocaine versus intravenous morphine sulfate in pain reduction in bone fractures. Design study: Randomized (Sealed Envelope), double blind (both medicine administrator and patient are not aware of type of medicine.) The study population: The patients with bone fracture. Inclusion criteria: All patients 15-65 years of age with long or short upper or lower bone fracture. Exclusion criteria: Persons under 15 years; People over 65 years; Pregnant and lactating women; People with loss of consciousness; Hemodynamic disorder; Traumatic patients with evidence of intra abdominal or intra pelvic hemorrhage; Mental retard patients; History of allergy to lidocaine or morphine; People with underlying disease (coronary artery disease; Diabetes; Heart valvular disease; History of cardiac arrhythmia; Hypertension; Cerebrovascular disease; Seizure; History of liver or renal disease); History of heart drugs; History of addiction. The sample size: about 280. Intervention: Intravenous Lidocaine. Intervention time: After primary physical exam, cardiac monitoring and VAS score calculation. The primary outcome expected: pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052622423N1**
Registration date: **2015-10-21, 1394/07/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-21, 1394/07/29

Registrant information

Name

Hamide Shiri

Name of organization / entity

Ahvaz Jondi Shapoor University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 33738383

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahvaz Jondishapur University of Medical Sciences. Dr Saki Nader

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Analgesic effect of intravenous lidocaine versus intravenous morphine sulfate in pain reduction in long or short bones fractures of upper and lower limbs

Public title

Evaluation of Analgesic effect of intravenous lidocaine versus intravenous morphine sulfate in pain reduction in long or short bones fractures of upper and lower limbs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteris : All patients 15-65 years of age with long or short upper or lower bone fracture, referring to emergency ward of Imam Khomeini and Golestan hospital in Ahwaz city. Exclusion criterias: Persons under 15 years; People over 65 years; Pregnant and lactating women; People with loss of consciousness; Hemodynamic disorder ; Traumatic patients with evidence of intra abdominal or intra pelvic hemorrhage ; mental retard patients; History of allergy to lidocaine or morphine; People treated with NA; People with underlying disease (Coronary artery disease ; Diabetes; Heart valvular disease; history of Cardiac arrhythmia; Hypertention; Cerebrovascular disease; seizure; history of liver or renal disease); history of heart drugs; history of addiction

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization is accomplished with sealed envelopes.Both lidocaine and morphine are colorless and odorless.To homogenize their volume, drugs are vaccumed in a 10 cc syringe according to the name of the drug, which is inside the sealed envelope by a person other then the drug administrator and the total volume is raised up to 10 cc with distilled water.then it would be injected to the patient by administrator.The administrator is unawar of type of drug .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundi shapoor University of Medical Sciences

Street address

Ground floor, Vice Chancellor for research of Ahwaz Jundishapoor University of Medical

Sciences,university city, Ahwaz city

City

Ahvaz

Postal code

61357-15794

Approval date

2015-05-09, 1394/02/19

Ethics committee reference number

IR.AJUMS.REC.1394.63

Health conditions studied

1

Description of health condition studied

Fracture

ICD-10 code

S52

ICD-10 code description

Fracture of forearm

2

Description of health condition studied

fracture

ICD-10 code

S62

ICD-10 code description

Fracture at wrist and hand level

3

Description of health condition studied

fracture

ICD-10 code

S00-T98

ICD-10 code description

Other fractures of long or short bones

4

Description of health condition studied

Fracture

ICD-10 code

S42

ICD-10 code description

Fracture of shoulder and upper arm

5

Description of health condition studied

fracture

ICD-10 code

S72

ICD-10 code description

Fracture of femur

6

Description of health condition studied

fracture

ICD-10 code

S82

ICD-10 code description

Fracture of lower leg, including ankle

7

Description of health condition studied

fracture

ICD-10 code

S92

ICD-10 code description

Fracture of foot, except ankle

Primary outcomes

1

Description

pain

Timepoint

0-5-10-15-20-25-30-minute

Method of measurement

vas score

Secondary outcomes

1

Description

Blood pressure

Timepoint

0-10-15-20-25-30 minute

Method of measurement

with manometer

2

Description

Pulse rate

Timepoint

0-10-15-20-25-30 minute

Method of measurement

Count per minute

3

Description

spo2

Timepoint

0-10-15-20-25-30 minute

Method of measurement

with pulse oximetry

4

Description

respiratory rate

Timepoint

0-10-15-20-25-30 minute

Method of measurement

Count per minute

Intervention groups

1

Description

Control group:Intra venous morphine 0.1mg/kg bolus during 2 minutes

Category

Treatment - Drugs

2

Description

Intervention group:Intra venous Lidocaine 1.5 mg/kg bolus during 2 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr Arash Forouzan

Street address

Golestan educational and medical center, Farvardin street, Ahwaz city

City

ahwaz

2

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr Hamide shiri

Street address

Imam Khomeini educational and medical center, Azadegan street, Ahwaz city

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ahwaz Jundishapoor University of Medical Sciences

Full name of responsible person

Dr Saki Nader

Street address

Ground floor, Vice chancellor for research of Ahwaz Jundishapoor University of Medical Sciences, univercity city, Ahwaz city

City

Ahwaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research Ahvaz Jundishapoor
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 Jundishapoor University of Medical Sciences

Full name of responsible person

Hamide Shiri

Position

MD, Emergency medicine resident

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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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*