Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of venous lidocaine efficacy with intravenous morphine in reducing acute pain in patients with trauma

Protocol summary

Study aim
Effectiveness of intravenous lidocaine in comparison with venous morphine in reducing acute pain due to organ trauma

Design
This randomized blind study with parallel groups will be performed on 60 patients with acute extremity trauma.Patients will be randomly divided into two groups by throwing coins.The first intervention group will receive 0.1mg / kg morphine sulfate as intravenous injection.The second intervention group will receive 1.5 mg / kg lidocaine as intravenous injection.

Settings and conduct
This randomized blind study will be carried out in patients with acute extremity trauma referring to the Peymaniyeh Hospital of Jahrom. Patients who are eligible for inclusion in the study will be divided into two groups by throwing coins. The first group will receive 0.1 mg / kg morphine sulfate and the second group will receive 1.5 mg / kg lidocaine as a slow intravenous injection. Both groups at the time of referral and then 15 minutes, 30 minutes, 45 minutes and 60 minutes after administration of the drug The use of the numerical scale of pain will be studied. In the present study, the patients in the study, the investigator and the data collector, and the data monitoring committee will be unaware of which individuals are in the group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with acute trauma of the upper or lower extremity ؛ dislocation, fracture as the main cause of recurrence ؛ and the need for pain relief due to severe limb pain. exclusion criteria: Patients with Disorders levels of consciousness؛ Hemodynamic impairment during drug administration and the susceptibility to Lidocaine and Morphine

Intervention groups
The first intervention group will receive 0.1mg / kg morphine sulfate as intravenous injection.The second intervention group will receive 1.5 mg / kg lidocaine as intravenous injection.

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180805040712N2**
Registration date: **2019-03-10, 1397/12/19**
Registration timing: **retrospective**

Last update: **2019-03-10, 1397/12/19**
Update count: **0**

Registration date
2019-03-10, 1397/12/19

Registrant information
Name
Mohammad safaei saruei
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3620 9889
Email address
m.safaie@jums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-27, 1396/10/06

Expected recruitment end date
2019-01-31, 1397/11/11

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of venous lidocaine efficacy with intravenous morphine in reducing acute pain in patients with trauma

Public title

Comparison of venous lidocaine with venous morphine in reducing acute pain due to trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute upper or lower limb trauma including soft tissue injury Fractures as the main cause of referral Dislocation Need to get analgesia due to extreme pain in the limbs

Exclusion criteria:

Disorders of consciousness Hemodynamic Disorders During Injection Sensitization Lidocaine and Morphine

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be divided into two groups by throwing coins. One of the groups will receive intravenous lidocaine and another group will receive intravenous morphine.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In the present study, the patients participating in the study, the researcher, the data collector and the data monitoring committee will be unaware of which individuals are in the group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jahrom University of Medical Sciences

Street address

Pardis Building, Motahari Blvd. ,Jahrom

City

Jahrom

Province

Fars

Postal code

7414846199

Approval date

2017-07-05, 1396/04/14

Ethics committee reference number

IR.JUMS.REC.1396.032

Health conditions studied

1

Description of health condition studied

Patients with limb trauma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intensity of pain

Timepoint

At the time of referral, then 15, 30, 45 and 60 minutes after the administration of the drug

Method of measurement

Using the numerical scale of pain assessment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group will receive 0.1mg / kg morphine sulfate as a slow intravenous injection.

Category

Treatment - Surgery

2

Description

Intervention group: The second intervention group will receive 1.5 mg / kg lidocaine as a slow intravenous injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Peymaniye hostpital

Full name of responsible person
اسماعیل رعیت دوست

Street address
Peymaniye Hostpital,Valiye Asr St, Jahrom City, Fars Province

City
Jahrom

Province
Fars

Postal code
74148-46199

Phone
+98 71 5423 0085

Email
navidkalani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Kavoos solhjoo

Street address
Jahrom, the end of Motahari Blvd, Pardis Building

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navidkalani@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Jahrom University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Esmaile raiyat dust

Position
Emergency Medicine Specialist

Latest degree
Specialist

Other areas of specialty/work
Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available