# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jun 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

**City**
Jahrom

**Province**
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**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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Jahrom, the end of Motahari Blvd, Pardis Building

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Jahrom University of Medical Sciences

**Full name of responsible person**
Esmaile raiyat dust

**Position**
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**Latest degree**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Jahrom University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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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