

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

A clinical trial for comparison between intravenous ketamine with intravenous morphine for pain reduction in acute lower limb trauma

Protocol summary

Summary

Objectives: To compare the analgesic effects of intravenous (IV) ketamine with IV morphine sulfate in acute lower limb trauma. **Design:** This is a single center, phase 1, randomized double blinded clinical trial performed on 60 patients presenting with acute limb trauma to the Emergency Department (ED). Patients are consecutively assigned to 2 groups to receive ketamine or morphine for analgesia by block randomization method. Blinding is performed by assigning numbers to syringes. The researcher, nurse, and patient are unaware of drug administered in the study period. **Setting and conduct:** This study is performed in Bahonar Academic Hospital in Kerman, Iran. Data collection and monitoring are performed by a resident of Emergency Medicine (EM) and an attending physician of EM, respectively. **Participants:** Patients over 18 years of age with acute lower limb trauma are included in the study. Patients with hypersensitivity to ketamine or morphine, unstable hemodynamic signs, altered mental status, signs of increased Intra-cerebral pressure, any distracting injuries, neuropathies, history of cardiovascular disease, and disagreement to participate will be excluded. **Interventions:** Enrolled patients will be randomized into 2 groups with equal sizes (30 patients) receiving either IV ketamine or IV morphine. After signing informed consent by each patient, All patients will undergo pain intensity measurement by Numeric Rating Scale (NRS) from 0 to 10 and receive either IV ketamine (0.5mg/kg) or IV morphine (0.1mg/kg) by slow bolus administration in 5 minutes). After completion of drug administration, pain score will be re-assessed in 5, 10, and 30 minutes. **Outcomes:** Pain scores at 5, 10, and 30 minutes after injection are considered as primary outcomes. Vital signs during injection and re-evaluations will be recorded and any adverse reactions to each drug will be documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050515941N3**
Registration date: **2016-08-25, 1395/06/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-25, 1395/06/04

Registrant information

Name

Amirhossein Mirafzal

Name of organization / entity

Kerman University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1247 4638

Email address

mirafzal@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-07-01, 1395/04/11

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial for comparison between intravenous ketamine with intravenous morphine for pain reduction in acute lower limb trauma

Public title

Ketamine vs. morphine for limb injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients over 18 years of age presenting with acute lower limb trauma. Exclusion criteria: hypersensitivity to ketamine or morphine; unstable hemodynamic signs (hypotension, clinical signs of shock); altered mental status or mental illness; signs of increased Intra-cerebral or intra-ocular pressure; any distracting injuries; peripheral neuropathies; history of cardiovascular disease and hypertension; disagreement to participate in the study will be excluded.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of Kerman University of Medical Sciences

Street address

Deputy of Research and Technology of Kerman University of medical Sciences, Jahad St., Kerman, IRAN

City

Kerman

Postal code**Approval date**

2015-07-11, 1394/04/20

Ethics committee reference number

IR.KMU.REC.1394.219

Health conditions studied**1****Description of health condition studied**

Upper and Lower limb trauma

ICD-10 code

S40 to S99

ICD-10 code description

Injuries to shoulder and upper arm to injuries to ankle and foot

Primary outcomes**1****Description**

Pain score using Numeric Rating Scale (NRS)

Timepoint

5, 10 and 30 minutes after injection

Method of measurement

by asking the patient

Secondary outcomes**1****Description**

No secondary outcome

Timepoint

no secondary outcome

Method of measurement

no secondary outcome

Intervention groups**1****Description**

Ketamine 0.5 mg/kg by single slow IV bolus

Category

Treatment - Drugs

2**Description**

Morphine sulfate 0.1 mg/kg by single slow IV bolus

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bahonar Academic Hospital

Full name of responsible person

Amirhossein Mirafzal

Street address

Bahonar Hospital, Gharani St., Bagh-e Melli cross St.,
Kerman, Iran

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Amirhossein mirafzal

Full name of responsible person

Amirhossein Mirafzal

Street address

No 92, Hamzeh St, Hamzeh Blvd, Kerman, Iran

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Amirhossein mirafzal

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

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal

Position

Assistant Professor

Other areas of specialty/work

Street address

No 92, 9th Hamzeh St, Hamzeh Blvd, Kerman, Iran

City

Kerman

Postal code

Phone

+98 34 3246 5958

Fax

Email

mirafzal@kmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal

Position

Assistant Professor

Other areas of specialty/work

Street address

No 92, 9th Hamzeh St, Hamzeh Blvd, Kerman, Iran

City

Kerman

Postal code

Phone

+98 34 3246 5958

Fax

Email

mirafzal@kmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal

Position

Assistan Professor

Other areas of specialty/work

Street address

No 92, 9th Hamzeh St, Hamzeh Blvd, Kerman, Iran

City

Kerman

Postal code

Phone

+98 34 3246 5958

Fax

Email

mirafzal@kmu.ac.ir

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