

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Intravenous Ketamine with Morphine in Pain Relief of Long Bones Fractures

Protocol summary

Summary

The selective medication for pain control in many clinical situations. Ketamine has been introduced as an alternative for morphine in some studies. However, the efficacy of its solitary use has not yet been evaluated. In this double-blind clinical trial, patients with long bone fractures will randomly divide into two groups of treatment with intravenous (IV) morphine at a dose of 0.1 mg/kg and treatment with IV ketamine at a dose of 0.5 mg/kg. Pain severity of the patients will be recorded before and 10 minutes after injection base on Numeric Rating Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042812072N3**
Registration date: **2015-05-24, 1394/03/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-24, 1394/03/03

Registrant information

Name

Mehrdad Esmailian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 3482

Email address

m_esmailian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2013-12-31, 1392/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Intravenous Ketamine with Morphine in Pain Relief of Long Bones Fractures

Public title

Ketamine with Morphine in Pain Relief

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: fractures of long bones. Exclusion criteria: drug abuse; trauma to the head; symptoms and signs of increased intracranial pressure; a decrease in consciousness level; respiratory problems; a history of asthma

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **126**

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

Isfahan University of Medical sciences

Street address

Azadi Ave.

City

Isfahan

Postal code

Approval date

2011-08-23, 1390/06/01

Ethics committee reference number

65892

Health conditions studied

1

Description of health condition studied

Long Bone Fracture

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

2

Description of health condition studied

Long Bone Fracture

ICD-10 code

S72.0

ICD-10 code description

Fracture of neck of femur

Primary outcomes

1

Description

Pain Severity

Timepoint

before drug injection and 10 minute after drug injection

Method of measurement

Numeric RatingScale

Secondary outcomes

1

Description

Respiratory Complications

Timepoint

before drug injection and 30 minutes after drug injection

Method of measurement

Numeric Rating Scale

2

Description

Nausea and Vomiting

Timepoint

before drug injection and 30 minutes after drug injection

Method of measurement

Numeric Rating Scale

Intervention groups

1

Description

Intervention group receiving IV ketamine at a dose of 0.5 mg/kg. The severity of pain will register before injection and 10 minutes after injection based on Numeric Rating Scale. In cases in which pain will not subside after 10 minutes (a decrease in pain severity equal to or less than 3), the patient will receive half the initial dose again.

Category

Treatment - Drugs

2

Description

Control group receiving IV morphine at a dose of 0.1 mg/kg. The severity of pain will register before injection and 10 minutes after injection based on Numeric Rating Scale. In cases in which pain will not subside after 10 minutes (a decrease in pain severity equal to or less than 3), the patient will receive half the initial dose again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mehrdad Esmailian

Street address

Sofeh Blv.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Reza Azizkhani

Street address

Azadi Ave.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Mehrdad Esmailian

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

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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