Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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
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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 registere before injection and 10 minutes after injection based on Numeric Rating Scaleth. 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 registere 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.
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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
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Person responsible for updating data

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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