Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing effects of low dose injectable morphine and ketamine in patients with long bone fracture pain

Protocol summary

Summary

Objectives: Also, attempts are made to compare the effect of two sedatives, intravenous injection of morphine and ketamine, on the reduction of pain caused by long-bone fracture among the patients referring to the emergency ward of Imam Khomeini Medical and Educational Center during 4 hours that patients are present in this ward. Design: Randomized, double blind, without control and with placebo, single central, stage three trial Participants including major eligibility criteria:The research population includes 18 to 65 year old people with long bone fracture in their upper or lower extremities, which is caused by direct or blunt trauma, referring to the emergency ward of the hospital; they need inject-able sedatives to control their pain. Inclusion criteria: Fracture of long bones in upper or lower extremities caused by blunt and direct trauma referring to the emergency ward; needing inject-able sedative Exclusion criteria: Pregnant or breastfeeding women; pressure of above 18 or below 90 mm Hg; heart rate of below 50 or above 150 per minute; respiration rate of below 10 or above 30 per minute; reduced consciousness; use of inject-able drugs; open fracture; compartment syndrome; lack of tendency to participate in the project; receiving sedatives before the research The sample size is calculated to be 156 patients. Research intervention(s): Intervention group: Ketamine, 0.5mg / kg intravenous injection (by Abidi Pharmaceutical Company, Iran), one dose, zero minute of the study Intervention group: Morphine, 1.0mg / kg slow injection (by Abidi Pharmaceutical Company, Iran), one dose, zero minute of the study Intervention time: Zero minute of the study main outcome measures: Pain; intervention start; 30, 60, 90, 120, 180 and 240 min after the intervention start; visual scale of pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041221480N6**
Registration date: **2017-07-26, 1396/05/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-26, 1396/05/04

Registrant information

Name
Fatemeh Jahanian
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of low dose injectable morphine and

ketamine in patients with long bone fracture pain

Public title
Comparing effects of morphine and ketamine on pain relief
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Fracture of long bones in upper or lower extremities caused by blunt and direct trauma referring to the emergency ward; needing inject-able sedative Exclusion criteria: History of psychiatric, liver and kidney diseases, stroke, asthma and other cardiac and respiratory diseases; weight of below 45 or above 155 kg; pregnant or breastfeeding women; pressure of above 18 or below 90 mm Hg; heart rate of below 50 or above 150 per minute; respiration rate of below 10 or above 30 per minute; reduced consciousness; blow to the head or eyes; multiple trauma; allergy to the sedatives used in the research; drug addiction; use of inject-able drugs; fracture in the parts other than long bones; fracture with dislocation or fracture with extreme displacement that requires a reduction ; open fracture; compartment syndrome; lack of tendency to participate in the project; receiving sedatives before the research
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **156**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In the present Study, random numbers with randomization is used.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Sciences, Vice Chancellor for Research, Moalem Square, Sari, Iran
City
Sari
Postal code
Approval date
2016-04-13, 1395/01/25
Ethics committee reference number
IR.MAZUMS.REC.95-1954

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
M79
ICD-10 code description
Other soft tissue disorders, not elsewhere classified

Primary outcomes

1

Description
Pain
Timepoint
Start the intervention, in minutes (30, 60, 90, 120, 180, 240) after the intervention
Method of measurement
Visual scale of pain

Secondary outcomes

1

Description
Blood Pressure
Timepoint
0,30,60,120,180,240 minutes after intervention
Method of measurement
MmHg With manometer

2

Description
Respiratory rate
Timepoint
0,30,60,120,180,240 minutes after intervention
Method of measurement
Count the respiration rate

Intervention groups

1

Description
Intervention group: Ketamine, 0.5mg / kg intravenous injection (by Abidi Pharmaceutical Company, Iran), one dose, zero minute of the study

Category
Treatment - Drugs

2

Description
Intervention group: Morphine, 1.0mg / kg slow injection (by Abidi Pharmaceutical Company, Iran), one dose, zero minute of the study
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini Hospital of Sari
Full name of responsible person
Vahide Azarfar
Street address
University of Medical Sciences, Valiasr Highway, Juibar Crossroad, Imam Square, Sari, Iran
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
Street address
University of Medical Sciences, Valiasr Highway, Juibar Crossroad, Imam Square, Sari, Iran
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mazandaran 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
Mazandaran University of Medical Sciences
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Position
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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