

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

fjahanian@mazums.ac.ir

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

Full name of responsible person

Vahide Azarfar

Position

Residency Of Emergency Medicine

Other areas of specialty/work**Street address**

Emergency Medicine Department, Imam Khomeini Hospital, Amir Mazandarani Street, Sari, Iran

City

Sari

Postal code**Phone**

+98 11 3304 4866

Fax**Email**

azr1356@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University Of Medical Sciences

Full name of responsible person

Fatemeh Jahanian

Position

Emergency Medicine Specialist

Other areas of specialty/work**Street address**

Emergency Medicine Department, Imam Khomeini Hospital, Amir Mazandarani Street, Sari, Iran

City

Sari

Postal code**Phone**

+98 11 3304 4866

Fax**Email**

SHEILAML@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Vahide Azarfar

Position

Residency of Emergency Medicine

Other areas of specialty/work**Street address**

Emergency Medicine Department, Imam Khomeini Hospital, Amir Mazandarani Street, Sari, Iran

City

Sari

Postal code

Phone

+98 11 3304 4866

Fax

Email

azr1356@yahoo.com

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