

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Efficacy and safety of morphine-ketamine combination in comparison with morphine alone in acute pain management among patients who admitted to emergency with limb fracture

Protocol summary

Summary

Ketamine, as a phencyclidine derivative, has an analgesic and sedative effect with the lowest respiratory depression and hypotension. Many authorities have attempted to disclose positive effects of ketamine as an adjuvant in opioid drugs like morphine despite the global need to conducting additional high sample sized surveys yet. The current study was conducted to investigate analgesic effects of ketamine-morphine combination whilst morphine alone in limb fractures considering side effects and safety in emergency room. Sample size in this study is 192 patients (a 95% confidence interval was considered and P value[<]0.05 was regarded as significance). Patients in the age range of 18-50 years with acute pain because of limb fracture will consider if have consent to enroll the study and ready to collaborate the investigators. People with long-term opioid use, pregnant women, breast feeding and allergy to ketamine or morphine, asthma, renal failure, acute coronary syndrome, and unstable vital signs will exclude. Participants recruit to enroll one of the A (Morphine) or B (Morphine-Ketamine) groups randomly using random table numbers. Neither the patients nor the physicians know about the used analgesics in each group and case number. We ask patients about their severity of pain to get a base for Numerical Rating Score before starting the treatment. In the case of Numerical Rating Score equal or greater than 4, 0.1mg/ kg bolus dose of morphine will be prescribed. All the variables such as vital signs, side effects, pain scores will be checked at consequent fifth, tenth, and 20th minutes to find any changes. A group as the control group use morphine sulfate 0.05mg/kg maintenance therapy after a bolus dose of morphine at the beginning and in investigation group, ketamine 0.2mg/kg use with morphine 0.05mg/kg after the first bolus dose of morphine. Adverse effects of the prescribed drugs, vital signs, and pain scores record. The

process will be performed every 20 minutes until the Numerical rating Score fall under 4, or past more than 2 hours from the beginning dosage. Keywords: Morphine, Ketamine, Acute pain, Limb Fracture

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052015620N5**

Registration date: **2015-08-17, 1394/05/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-17, 1394/05/26

Registrant information

Name

Alireza Majidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-12-28, 1391/10/08

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of morphine-ketamine combination in comparison with morphine alone in acute pain management among patients who admitted to emergency with limb fracture

Public title

Pain management in patients with limb fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 50 years, patients with Limbs trauma, Acute pain, confirmed limb fractures with imaging. Exclusion criteria: cases with opium addiction, any analgesic drug consumption prior coming to ED, pregnant women, any allergy to Ketamine or Morphine, history of chronic pain, asthma, renal failure, coronary disease, and unstable hemodynamic status were excluded.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **192**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

People who refer to a referral hospital, and after confirmed fracture recruit to enroll one of the A (Morphine) or B (Morphine-Ketamine) groups by non probability sampling available technique and we will use random number table. Neither the patients nor the physicians know about the used analgesics in each group and case.

Secondary Ids**1****Registry name****Secondary trial Id****Registration date**

2017-11-21, 1396/08/30

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Tabnak St., Evin, Chamran Highway, Tehran, Iran.

City

Tehran

Postal code**Approval date**

2013-06-30, 1392/04/09

Ethics committee reference number

13024-1086-136-1-1391

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

Upper limb injuries

ICD-10 code

S42.2/ S42

ICD-10 code description

Fracture of upper end of humerus, Fracture of shaft of humerus, Fracture of lower end of humerus, Fracture of shaft of ulna, Fracture of shaft of radius, Fracture of other parts of forearm

2**Description of health condition studied**

Lower limb injuries

ICD-10 code

S72.0/ S72

ICD-10 code description

Fracture of neck of femur, Fracture of shaft of femur, Fractures of other parts of femur, Fracture of upper end of tibia, Fracture of shaft of tibia, Fracture of fibula alone, Fractures of other parts of lower leg

3**Description of health condition studied**

Pain in limb

ICD-10 code

M79.6

ICD-10 code description

Pain in limb

Primary outcomes

1

Description

Age, Gender, Blood Pressure, Respiratory Rate, Numerical Rating Scale, Pulse Rate, Fracture Type

Timepoint

Fifth, tenth, 20th Minutes after each drug administration

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Drug side effects

Timepoint

Fifth, tenth, 20th Minutes after each drug administration

Method of measurement

Questionnaire

Intervention groups

1

Description

In the case of Numerical Rating Score equal or greater than 4, 0.1mg/kg bolus dose of morphine prescribe. All the variables such as vital signs, side effects, pain scores will check at consequent fifth, tenth, and 20th minutes to find any changes. A group as the control group use morphine sulfate 0.05mg/kg maintenance therapy after a bolus dose of morphine at the beginning. Adverse effects of the prescribed drugs, vital signs, and pain scores record. The process perform every 20 minutes until the Numerical Rating score fall under 4, or from beginning dose more than 2 hours past.

Category

Treatment - Drugs

2

Description

In the case of Numerical Rating Score equal or greater than 4, 0.1mg/kg bolus dose of morphine prescribe. All the variables such as vital signs, side effects, pain scores will check at consequent fifth, tenth, and 20th minutes to find any changes. In investigation group, ketamine 0.2mg/kg use with morphine 0.05mg/kg after the first bolus dose of morphine. Adverse effects of the prescribed drugs, vital signs, and pain scores record. The process perform every 20 minutes until the Numerical rating score fall under 4, or from beginning dose more than 2 hours past.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Alireza Majidi

Street address

Emergency Department, Shohadaye Tajrish Hospital, Tajrish Sq., Tehran, Iran

City

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2

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Zein Alabedin Chaboksavar

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Emergency Department, Emam Hossein Hospital, Shahid Madani St., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Third floor, Vice chancellor for research, Shahid Beheshti University of Medical Sciences, Tabnak St., Evin, Chamran Highway, Tehran, Iran.

City

Tehran

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, Shahid Beheshti 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
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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