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
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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
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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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
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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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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