Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Sub-dissociative dose of ketamine and morphine sulfate for acute pain control of patients with isolated limb injuries in the emergency department

Protocol summary

Study aim

Comparison of sub-dissociative dose of ketamine and morphine sulfate for acute pain control of patients with isolated limb injuries in the emergency department

Design

Phase 3 triple blinded randomized clinical trial with parallel groups. Sample size: 70 patients.

Settings and conduct

This study will be conducted in Imam Khomeini Hospital in Tehran, Iran, which is an academic hospital. This will be a triple blinded randomized clinical trialThe emergency department sees 70000 patients annually. Patients, the committee that monitors the response variable, and the analyzer will be blinded. All randomizations and drug preparations will be done by a single investigator who will not participate in patients enrollment, assessment, and analysis. Patients with isolated limb trauma who has pain intensity equal to or greater than 5 of 11 on NRS will receive intravenous morphine or ketamine randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Emergency department patients with isolated traumatic limb injuries with a pain score of 5 or more on a standard 11-point (0-10) numerical rating scale Exclusion criteria: Patients with altered mental status, Patients with unstable vital signs, Patients with known underlying hepatic or renal diseases, Pregnant patients, Non-consent patients, and Patients under the age of 18 or over the age of 55 years old

Intervention groups

The first intervention group: 0.1 mg/kg ketamine in 10 mL normal saline over 5 minutes intravenously. The second intervention group: 0.05 mg/kg morphine in 10 ml normal saline over 5 minutes intravenously.

Main outcome variables

Pain intensity; adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150213021063N6**
Registration date: **2020-07-20, 1399/04/30**
Registration timing: **retrospective**

Last update: **2020-07-20, 1399/04/30**
Update count: **0**

Registration date

2020-07-20, 1399/04/30

Registrant information

Name

Arash Safaie

Name of organization / entity

Tehran University of Medical Scieces- Sina Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

2016-01-21, 1394/11/01

Actual recruitment end date

2017-01-20, 1395/11/01

Trial completion date

2017-01-20, 1395/11/01

Scientific title
Comparison of Sub-dissociative dose of ketamine and morphine sulfate for acute pain control of patients with isolated limb injuries in the emergency department

Public title
Ketamine versus morphine for acute pain control
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Emergency department patients with isolated traumatic limb injuries with a pain score of 5 or more on a standard 11-point (0-10) numerical rating scale
Exclusion criteria:
Patients with altered mental status Patients with unstable vital signs Patients with known underlying hepatic or renal diseases Pregnant patients Non-consent patients Patients under the age of 18 or over the age of 55 years old
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **73**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be performed using random numbers table. The random numbers table itself will be made by the http://random.org website. The drugs will be prepared in blocks of similar looking 10 mL syringes allocated to the 2 intervention groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
All randomizations and drug preparations will be done by a single investigator who will not participate in patients enrollment, assessment, and analysis. The other investigators and patients will be blinded. Also the committee that monitor response variable will be blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Tehran University of Medical Sciences
Street address
Building No 1- Northern gate of the university- Poursina street- Qods street- Enghelab avenue.
City
Tehran
Province
Tehran
Postal code
1419733151
Approval date
2016-01-20, 1394/10/30
Ethics committee reference number
IR.TUMS.REC.1394.1710

Health conditions studied

1

Description of health condition studied
Acute pain due to trauma
ICD-10 code
G89.11
ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Pain intensity
Timepoint
Before drug administration, 5, 10, 15, 20, 25, and 30 minutes after drug administration
Method of measurement
Numeric rating scale

Secondary outcomes

1

Description
Adverse events
Timepoint
Patients will be monitored continuously for adverse events since drug administration till patient discharge.
Method of measurement
Specific occurred adverse event

Intervention groups

1

Description
Intervention group: 0.1 mg/kg ketamine in 10 mL normal saline over 5 minutes intravenously
Category
Treatment - Drugs

2

Description
Intervention group: 0.05 mg/kg morphine in 10 ml normal saline over 5 minutes intravenously
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Seyed Mojtaba Aghili
Street address
Chamran Highway, Baqerkhan Street
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Seyed Mojtaba Aghili
Position
Assistant professor of emergency medicine
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All unidentified IPD and statistical analyses are sharable.
When the data will become available and for how long
شروع دوره دسترسی 1 ماه پس از چاپ
To whom data/document is available
Data will be available for academic, scientific, or industrial institutes researchers.
Under which criteria data/document could be used
Data will be shared upon Written request of the individual researcher or the institute.
From where data/document is obtainable
Data will be shared by sending email to Arash Safaie. Email: aghili220@yahoo.com
What processes are involved for a request to access data/document
Data will be shared by sending email to Dr. Seyed Mojtaba Aghili. We will try our best to send you the requested data as soon as possible.
Comments