Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of low-dose (sub dissociative) ketamine with dexmedetomidine, and its comparison with morphine in controlling pain in patients with limb trauma referred to emergency department of Sina hospital

Protocol summary

Study aim

Determination of the effectiveness of low-dose ketamine with dexmedetomidine, and its comparison with morphine in controlling pain in patients with limb trauma referred to the emergency department

Design

Clinical trial, with a parallel-group, double-blind, randomized, phase 3 on 258 patients. Using Block Stratified Randomization software, Windows version 6.0 is randomly divided into two categories.

Settings and conduct

258 adult patients who were referred to the emergency department with pain due to limb trauma are randomly divided into two groups. After obtaining informed consent to participate in the study, they receive the drugs, then by comparing the scores they have suffered before and after taking the drug (at intervals of 5, 10, and 15 minutes after injecting the drug) and We will also discuss the possible benefits of this alternative method for its side effects.

Participants/Inclusion and exclusion criteria

Adult patients who have been referred to the Sina Hospital emergency department with limb trauma. Patients with the following characteristics will not be included in the study 1. Pain score ≤ 5, 2. Pregnancy and post-partum women, 3. Altered mental status, 4. Allergy to ketamine or morphine or dexmedetomidine, 5. Bodyweight ≤ 46 kg or ≥ 115, 6. Unstable vital signs: BP≤ 90 mmHg or ʌ 180 mmHg, PR≥150 or ≤50 bits/min, RR≤10 or ≥30, 7. History of the recent head or eye trauma, 8. History of seizure, 9. History of elevated ICP, 10. Chronic pain, ١١. Renal or hepatic failure, 12. Substance or alcohol abuse, 13. Documented psychiatric disorders, 14. Opium addiction, 15. Recent use of narcotic analgesics

Intervention groups

Two groups of intravenous sub dissociative ketamine (0.3 mg/kg) with (1 mcg/kg) intravenous dexmedetomidine or intravenous morphine (0.1 mg/kg).

Main outcome variables

Pain intensity; blood pressure; heartbeat; Number of breaths; drug side effects; rescue analgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220120053770N1**
Registration date: **2022-02-12, 1400/11/23**
Registration timing: **prospective**

Last update: **2022-02-12, 1400/11/23**
Update count: **0**

Registration date

2022-02-12, 1400/11/23

Registrant information

Name

MohammadMatin Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 0317

Email address

mmatinmoradi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of low-dose (sub dissociative) ketamine with dexmedetomidine, and its comparison with morphine in controlling pain in patients with limb trauma referred to emergency department of Sina hospital

Public title

Evaluation of the effectiveness of low-dose ketamine (Sub dissociative) with dexmedetomidine in controlling pain in patients with limb trauma referred to emergency department

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (older than 18 years old) gave pain more than five points limb trauma pain obtaining the informed consent

Exclusion criteria:

Pain score ≤5 Pregnancy and post-partum women Altered mental status Allergy to ketamine or fentanyl Body weight ≤ 46 kg or ≥ 115 Unstable vital signs: BP≤ 90 mmHg or ≥ 180 mmHg , PR≥150 or ≤50 bits/min , RR≤10 or ≥30 History of recent head or eye trauma History of Siesure History of elevated ICP Chronic pain Renal or hepatic failure Substance or alcohol abuse Documented psychiatric disorders Opium addiction Recent use of narcotic analgesics

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **258**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients have already been randomly divided into two categories by a statistician using Block Stratified Randomization Windows version 6.0 software, and their randomization list has been provided to the researcher. Each day five participants from those two groups will be involved and they will be ordered randomly . Every morning a person not involved in the study or patient care prepared study packages and stored them in a locked drawer. When each new subject was enrolled by an attending emergency physician, they were allocated to the next number based on the randomization schedule. The physician then picked up the matched, numbered package from the drawer.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient does not know the type of drug used. Also, to observe the principle of blinding in the study, the researcher and the person who follows and records the patient's pain are two different people, ie one person enters the patient and follows and another person selects and prescribes the patient's medication. The person following the patient will not be aware of the medication the patient has taken.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Sina Hospital

Street address

Sina Hospital

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2022-01-17, 1400/10/27

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1400.117

Health conditions studied

1

Description of health condition studied

Pain management of limb trauma in emergency department

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description
pain numerical rating scale
Timepoint
Intervals of 5, 10, 15, 30 minutes
Method of measurement
requires the patient to rate their pain (0–10) where 0 is no pain and 10 is the worst pain imaginable

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intravenous ketamine with sub dissociative dose (0.3 mg / kg) with intravenous dexmedetomidine (1 mcg / kg)
Category
Treatment - Drugs

2

Description
Intervention group: Intravenous morphine (0.1 mg / kg)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
MohammadMatin Moradi
Street address
Sina Hospital
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
حسین قناعتی
Street address
Tehran University of Medical Science
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 6405 3334
Email
okazi@tums.ac.ir
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
Alireza Baratloo
Position
Research Associate
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Sina Hospital
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
arbaratloo@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Jalali
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Sina Hospital
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
a.jalall85@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
MohammadMatin Moradi
Position
Medical Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Sina Hospital
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
mmatinmoradi@yahoo.com

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 collected data will be available
When the data will become available and for how long
6 months after publication
To whom data/document is available
Data will be available for Academic researchers and scientists
Under which criteria data/document could be used
Statistical analysis of data
From where data/document is obtainable
contact mmatininmoradi@yahoo.com
What processes are involved for a request to access data/document
After receiving the application, the requested information will be provided within one month
Comments