Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Intravenous and Intranasal Ketamine and Intravenous Morphine in Pain Relief of Bone Fractures

Protocol summary

Study aim
Intranasal and intravenous ketamine and morphine will be compared in the control of bone fracture pain.

Design
this study is a double blind randomized clinical trial. 153 patients will be included in this study. patients will be divided in 3 groups. Group 1: intravenous ketamine Group 2: intranasal ketamine Group 3: intravenous morphine

Settings and conduct
This study will be conducted in the emergency department of Imam Reza Hospital in Tabriz. Patients will be randomly divided into one of 3 groups upon arrival. The patient and the investigator who will measure the outcome will be blinded to the study. The first researcher and the caring nurse will know about the drugs and the groups.

Participants/Inclusion and exclusion criteria
All adult with bone fracture will be included in the study. The exclusion criteria include the following: Taking painkillers before entering the emergency room Head injury or loss of consciousness The existence of contraindications for the use of ketamine (history of cardiovascular disease, presence of symptoms of increased intracranial pressure, liver dysfunction, psychosis and pregnancy) Ketamine sensitivity Presence of contraindications for morphine use (respiratory depression, asthma, simultaneous use of monoamine oxidase inhibitors, opioid abuse, gastrointestinal obstruction) Hypersensitivity to morphine Lack of consent to participate in the study

Intervention groups
In the first group, patients will receive ketamine at a dose of 0.5 mg/kg body weight intravenously and four puffs of normal saline intranasally as a placebo. The second group will receive ketamine at a dose of 1 mg/kg of body weight as an intranasal puff and 1 ml of normal saline intravenously as a placebo. The third group will receive morphine at a dose of 0.1 mg/kg body weight intravenously and four puffs of normal saline intranasal as a placebo.

Main outcome variables
pain reduction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140524017812N4**
Registration date: **2023-10-12, 1402/07/20**
Registration timing: **retrospective**

Last update: **2023-10-12, 1402/07/20**
Update count: **0**

Registration date
2023-10-12, 1402/07/20

Registrant information

Name
Gholamreza Faridaalaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3382 9540

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Intravenous and Intranasal Ketamine and Intravenous Morphine in Pain Relief of Bone Fractures

Public title
Comparison of Ketamine and Morphine in Pain Relief
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
all patients with bone fracture who refer the emergency ward.
Exclusion criteria:
previous use of analgesic head trauma or loss of consciousness counterindication to ketamine such as heart disease, ICP rise, hepatic failure, psychosis, pregnancy allergy to ketamine counterindication to morphine such as (respiratory depression, asthma, use of monoamine oxidase inhibitors, opioid abuse, gastrointestinal obstruction) allergy to morphine Lack of consent to participate in the study Hepatic failure pregnancy
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **153**
Randomization (investigator's opinion)
Randomized
Randomization description
Using block randomization, patients will be assigned to one of the above-mentioned three groups. The randomization sequence using appropriate block size will be generated by Random Allocation Software and determined by one of the individuals who did not participate in the current research. It is necessary to explain that the aforementioned randomization method reduces the possibility of predicting and manipulating the randomization process by people to zero and will lead to the balance of the size of the groups during and at the end of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
After the diagnosis of a patient with a bone fracture, the patients are randomly assigned to one of 3 groups. After taking the history and considering the inclusion and exclusion criteria, informed consent will be obtained by the researcher. The drug will be prepared by the researcher. Then the clinical caregiver will use the drugs in the patient without knowing the selected drug. The outcome evaluator will measure the effect of the drug and record it in the form. The data will be entered into SPSS software by the researcher and the statistical consultant will analyze the data.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
daneshgah street
City
tabriz
Province
East Azarbaijan
Postal code
5166813390
Approval date
2023-01-23, 1401/11/03
Ethics committee reference number
IR.TBZMED.REC.1401.953

Health conditions studied

1

Description of health condition studied
bone fracture pain
ICD-10 code
S42
ICD-10 code description
Fracture of shoulder and upper arm

2

Description of health condition studied
bone fracture pain
ICD-10 code
S32
ICD-10 code description
Fracture of lumbar spine and pelvis

3

Description of health condition studied
BONE FRACTURE PAIN

ICD-10 code
S82
ICD-10 code description
Fracture of lower leg, including ankle

4

Description of health condition studied
bone fracture pain
ICD-10 code
S72
ICD-10 code description
Fracture of femur

Primary outcomes

1

Description
pain
Timepoint
0-15-30-60 minute
Method of measurement
0-10 pain scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: intranasal ketamine. in this group, they will receive 1mg/kg nasal ketamine along with 1 cc of normal saline intravenously. Ketamine is manufactured by PANPHARMA, Germany. And it will enter the nostrils in the form of a spray and macrodroplet. The drug will be injected by the researcher or the patient's nurse. After the drug injection, the pain level will be measured by the clinical evaluator at 15, 30 and 60 minutes.
Category
Treatment - Drugs

2

Description
Intervention group: intravenous ketamine. In this group, ketamine 0.5mg/kg will be given intravenously along with 4 puffs of normal saline nasal spray. Ketamine is manufactured by PANPHARMA, Germany. The drug will be injected by the researcher or the patient's nurse. After the drug injection, the pain level will be measured by the clinical evaluator at 15, 30 and 60 minutes.
Category
Treatment - Drugs

3

Description
Control group: intravenous morphine. For the intravenous morphine group, morphine 0.1mg/kg intravenously will be used along with 4 puffs of normal saline spray. Morphine is manufactured by Daropakhsh Iran. The drug will be injected by the researcher or the patient's nurse. After the drug injection, the pain level will be measured by the clinical evaluator at 15, 30 and 60 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Gholamreza Faridaalaee
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
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Fax
+98 41 3334 4280
Email
research-vice@tbzmed.ac.ir
Web page address
https://researchvice.tbzmed.ac.ir/
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Gholamreza Faridaalaee

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The demographic data of the patients and the outcome will be published in the form of an article.

When the data will become available and for how long
After the article is published, access to the data will be possible.

To whom data/document is available
all researchers

Under which criteria data/document could be used
nothing

From where data/document is obtainable

contact with me.

What processes are involved for a request to access data/document

The information will be accessible after obtaining the permission of the research vice-chancellor of the university and sending the permission to myself.

Comments