

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 Faridaalae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 9540

Email address

faridaalae@tbzmed.ac.ir

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 Daropaksh 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 Faridaalae

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Web page address<https://imamreza.tbzmed.ac.ir/>**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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Daneshgah street

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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 Faridaalae

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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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