

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the analgesic effect of nebulized fentanyl and infusion of ketamine for pain management of long bone fractures

Protocol summary

Summary

The aim of present study is comparing the analgesic effect of ketamine infusion with nebulized fentanyl for control of pain in patients with long bone fractures in a double-blind randomized clinical trial, in participants admitted to the emergency department of Imam Khomeini and Golestan hospital of Ahvaz in 2016-2017. Inclusion criteria: age 18 to 55 years, exclusion criteria: passing more than 24 hours of fractures, fractures avulsion, head injury, a history of smoking or drug abuse, pregnancy and lactation, signs of alcohol drinking or consumption, loss of consciousness, difficulty in breathing, allergy to ketamine, and a history of seizures. After obtaining consent, eligible patients will be divided randomly into two groups (each group 68). For first group 5 mL of saline intravenously and 4 mg/kg of solution, 50 micrograms per ml of fentanyl that its volume with normal saline arrives to 5 cc, receive with nebulizer and for the second group 0.4 mg/kg ketamine will be infused within 10 minutes. Pain intensity will be recorded by visual pain scale (VAS) before and (5, 10, 15, 30 and 60 minutes) after intervention. If pain is not controlled or sustained after interventions, additional painkiller will be prescribed and information will be recorded. Finally, medication side effects (nausea, vomiting, hallucinations, difficulty breathing and drowsiness) will be evaluated in patients.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017031229801N2**

Registration date: **2017-06-17, 1396/03/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-17, 1396/03/27

Registrant information

Name

Saeid Sadeghiyan

Name of organization / entity

Jundishapur University of Medical Sciences

Country

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Phone

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b_sadeghian@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the analgesic effect of nebulized fentanyl and infusion of ketamine for pain management of long bone fractures

Public title

Comparison the analgesic effect of nebulized fentanyl and infusion of ketamine for pain management in patients with long bone fractures in a clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 55 years Exclusion criteria: passing more than 24 hours of fractures; Avulsion fractures; head injury (if the level of consciousness decreased); a history of smoking or drug abuse; pregnancy and lactation; signs of alcohol (alcoholic patients); loss of consciousness; difficulty in breathing; allergy to ketamine; a history of seizures

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study will be used a block randomisation method for randomisation.

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur Of Medical Sciences

Street address

Golestan Street, Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Sciences, University Town, Ahvaz

City

Ahvaz

Postal code

15794 - 61357

Approval date

2016-11-19, 1395/08/29

Ethics committee reference number

IR.AJUMS.REC. 1395 .553

Health conditions studied

1

Description of health condition studied

Long bone fractures

ICD-10 code

M84

ICD-10 code description

Disorders of continuity of bone

Primary outcomes

1

Description

Pain

Timepoint

Before the intervention, and (5, 10, 15, 30 and 60 minutes) after intervention

Method of measurement

Visual pain scale

Secondary outcomes

1

Description

Medication side effects

Timepoint

(5, 10, 15, 30 and 60) minutes after intervention

Method of measurement

vital signs monitoring and symptoms created after the intervention.

Intervention groups

1

Description

Intervention group: For first group 5 mL of saline intravenously and 4 micrograms per kilogram of solution, 50 micrograms per ml of fentanyl that its volume with normal saline arrives to 5 cc, receive with nebulizer within 10 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: for the second group 0.4 mg/kg ketamine within 10 minutes will be infused.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Doctor Afsaneh khazaeli, Resident

Street address

24 Metry, Department of Emergency Medicine, Imam khomeni Hospital, Ahvaz

City

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2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Doctor Afsaneh khazaeli, Resident

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Golestan Street, Department Of Emergency Medicine, Golestan Hospital, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Sciences

Full name of responsible person

Dr Behzad Sharif Zadeh

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Golestan Street, Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Sciences, University Town, Ahvaz

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Ahvaz

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor For Research Of Ahvaz Jundishapur 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**

Department of Emergency Medicine

Full name of responsible person

Dr Afsaneh khazaeli

Position

Resident

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Other areas of specialty/work

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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