Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparsion the effect of intranasal ketamine hydrochloride and intravenous morphine sulfate on pain severity of patients with limb fracture

Protocol summary

Summary

Objective: assessment the effect of intranasal ketamine hydrochloride and intravenous morphine sulfate on pain severity of patients with upper or lower limbs fracture. Design: clinical trial without blinding Randomization: patients will allocate to two equal groups of intranasal ketamine hydrochloride and intravenous morphine sulfate according to table of random numbers. Participants including major eligibility criteria: this study will conduct on 104 patients with trauma in Ahvaz Imam Khomaieni and Gholestan hospitals. Main inclusion criteria include age range of 15 to 64 years and having upper and lower limbs fracture, and main exclusion criteria include low of consciousness; hemodynamic instability; addiction to drugs or opioids; mental retardation and psychosis; chronic cardiovascular diseases; being pregnant and breastfeeding; intranasal ketamine hydrochloride and intravenous morphine sulfate contraindication. Intervention: patients in intranasal ketamine hydrochloride group will receive 1 mg/kg ketamine hydrochloride of 10 ml solution (which put in sterile nasal drop bottle) via inhalation. Patients in intravenous morphine sulfate group will receive 0.1 mg/kg morphine sulfate via intravenous. Main outcome measures (variables): pain severity Setting and conduct: pain severity will assess in 0, 5, 10, 15, 20, 25, and 30 minutes in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031027007N1**
Registration date: **2016-05-28, 1395/03/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-28, 1395/03/08

Registrant information

Name

Somayyeh Gharibi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahwaz Judishapur University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion the effect of intranasal ketamine hydrochloride and intravenous morphine sulfate on pain severity of patients with limb fracture

Public title

Comparison the effect of intranasal ketamine

hydrochloride and intravenous morphine sulfate on pain severity of patients with upper or lower limbs fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age range of 15 to 64 years; having upper and lower limbs fracture. Exclusion criteria: low of consciousness; hemodynamic instability; addiction to drugs or opioids; mental retardation and psychosis; chronic cardiovascular diseases; being pregnant and breastfeeding; intranasal ketamine hydrochloride and intravenous morphine sulfate contraindication.

Age

From **15 years** old to **64 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

City

Ahvaz

Postal code

6135715794

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.AJUMS.REC.1394.338

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

M79.6

ICD-10 code description

Pain in limb

Primary outcomes

1

Description

Pain severity

Timepoint

Before intervention and 5, 10, 15, 20, 25 and 30 minutes after intervention

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Vital sign

Timepoint

Before intervention and 5, 10, 15, 20, 25 and 30 minutes after intervention

Method of measurement

Cardiopulmonary monitoring

Intervention groups

1

Description

Patients in intranasal ketamine hydrochloride group will receive 1 mg/kg ketamine hydrochloride of 10 ml solution (which put in sterile nasal drop bottle) via inhalation.

Category

Treatment - Drugs

2

Description

Patients in intravenous morphine sulfate group will receive 0.1 mg/kg morphine sulfate via intravenous

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Emam Khomeini hospital
Full name of responsible person
Arash Forouzan
Street address
Emam Khomeini hospital, Ahvaz, Khuzestan
City
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2

Recruitment center
Name of recruitment center
Ahvaz Golestan hospital
Full name of responsible person
Somayyeh Gharibi
Street address
Golestan hospital, Golestan road, Ahvaz, Khuzestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahwaz Judishapur University of Medical Sciences
Full name of responsible person
Nader Saki
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Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan
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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
Vice chancellor for research, Ahwaz Judishapur 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
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Full name of responsible person
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Resident of emergency medicine
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Person responsible for updating data

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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