Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of analgesic effect of intranasal ketamine versus intravenous ketamine in isolated orthopedic trauma patients

Protocol summary

Summary

The use of intranasal route for delivering medication such as ketamine, provides an efficient and relatively painless way for analgesia delivery. In a double-blind randomized controlled trial study, patients with age between 16 to 60 years, who are present by isolated orthopedic trauma and pain VAS score of more than 50 mm, enrolled in the study, considering inclusion and exclusion criteria. The sample size estimates 77 patients in each group based on Alpha 5% and 90% power and 10% as loss potential. Patients will divide in two groups randomly. Group A and B will be treated with nasal ketamine- intravenous sterile water and intravenous low dose ketamine- nasal sterile water respectively. Patients & researchers and analysts will be blind to groups of study. The VAS reduction and complications at time 0, 5, 10, 20 and 30 minute will recorded and then the difference between these values is evaluated by statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061722777N1**
Registration date: **2015-08-12, 1394/05/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-08-12, 1394/05/21

Registrant information

Name

Abdolghader Pakniyat

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of intranasal ketamine versus intravenous ketamine in isolated orthopedic trauma patients

Public title

analgesic effect of intra-nasal ketamine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with isolated trauma with fracture in the upper or lower extremities; aged between 16 and 60 years old; with Visual Analogue Scale pain score of more than 50 mm. Exclusion criteria: Patient’s refusal to participate in the study; having an underlying medical condition such as migraine, cardiac ischemia, schizophrenia, addiction, history of allergy to opiates or ketamine, head trauma or loss of consciousness; blood pressure of more than 180/100; vital signs Instability

before and during the study; pregnancy; nasal deformity or injury which prevents nasal medication administration; any inability to express their pain during the study; consumption of high doses of analgesics within the last 4 hours, such as tramadol, methadone and opiates; presence of other trauma.

Age
From **16 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **154**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences Ethic Comittee

Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak University of Medical Sciences

City
Arak

Postal code
3819693345

Approval date
2015-05-11, 1394/02/21

Ethics committee reference number
Ir.arakmu.rec.1394.25

Health conditions studied

1

Description of health condition studied
fracture of upper limb , fracture of lower limb

ICD-10 code
T10,T12

ICD-10 code description
Fracture of upper limb, level unspecified,Fracture of lower limb, level unspecified

Primary outcomes

1

Description
pain reduction

Timepoint
in 0, 5 ,10 , 20 and 30 min

Method of measurement
Vas Score

Secondary outcomes

1

Description
dizziness, nausea, pain, burning throat, amnesia, headache, pain or burning sensation

Timepoint
in 5 , 10 , 20 , 30 min

Method of measurement
physical examination

Intervention groups

1

Description
Intervention1 (case group): In Group A, patients receive a dose of 0.4 mg / kg intranasal ketamine initially by atomizer (dividing the dose in half and administering each half-dose per each nostril), and the same volume of intravenous Sterile water as placebo. Drugs' dose are calculated based on patient weight, intravenous and intranasal will be labeled as v (vein) and n (nasal) for group (A) respectively. VAS score and complication such as dizziness, nausea, pain, sour throat, amnesia, headache, pain or inflammation inside the nose will be recorded at times of 5, 10, 20 and 30. Patients whose VAS scale in T10; is reduced less than 13 mm (minimal clinically significant change noticeable by patients), were excluded from the study and routine analgesia administration and monitoring will be performed, also in the cases with noticeable pain reduction (more than 13 mm), but without acceptable pain reduction (at least 30 mm), a dose of 0.4 mg / kg intranasal ketamine (up to total dose of 0.8 mg /kg) should be re-injected at T10 and T20, along with placebo. If acceptable pain reduction is not achieved at T30, 0.05 mg / kg of intravenous morphine with routine monitoring as V (m) will be administrated in order to control the pain. During investigation, Patients will be monitored regarding vital signs and consciousness. They will be discharged only when they fully recover their consciousness.

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Description
Control group: in group (B), patients receive 0.2 mg / kg ketamine intravenously initially and the same volume of nasal sterile water as placebo. Drugs' dose are calculated based on patient weight. Intravenous and intranasal will be labeled as v (vein) and n (nasal) for group (B) respectively. VAS score and complication such as dizziness, nausea, pain, sour throat, amnesia, headache, pain or inflammation inside the nose will be recorded at times of 5, 10, 20 and 30. Patients whose VAS scale in T10; is reduced less than 13 mm (minimal clinically significant change noticeable by patients), were excluded from the study and routine analgesia administration and monitoring will be performed, also in the cases with noticeable pain reduction (more than 13 mm), but without acceptable pain reduction (at least 30 mm) at T10, T20 and T30, 0.1 mg / kg ketamine (up to total dose of 0.4 mg /kg) should be re-injected intravenously along with intranasal placebo. If acceptable pain reduction is not achieved by T30, 0.05 mg / kg of intravenous morphine with routine monitoring as V (m) will be administrated in order to control the pain. During investigation, Patients will be monitored regarding vital signs and consciousness. They will be discharged only when they fully recover their consciousness.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Emergency Trauma Center

Full name of responsible person
Abdolghader Pakniyat

Street address
Vali-asr Str, Emergency Medicine Department, Vali-asr Hospital

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Abdolghader Pakniyat

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A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak University of Medical Sciences

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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
Arak 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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Other areas of specialty/work

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City

Postal code

Phone

00

Fax

Email

Web page address

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