

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

Objectives: Comparison of analgesic effects and complication of intravenous low dose Ketamine versus intravenous Morphine Design: In a prospective; single-site; double-blind randomized controlled trial phase 3, 606 patients aged between 15 to 55 years old with isolated lower or upper limb orthopedic injury who have visual analog score of pain more than 50 mm, enrolled to the study considering inclusion and exclusion criteria Setting and conduct: The eligible patients will be simply randomized in two treatment groups by using of randomized numbers table. The sample size estimates 303 patients in each group based on Alpha 5% and 90% power and 20% as loss potential. Group A and B will be treated with intravenous Ketamine 0.25 mg/kg and intravenous Morphine 0.1 mg/kg respectively. Patients & investigators will be blind to groups of study. Main outcome measures: The reduction in visual analog score of pain and complications at 0, 5th, 10th, 20th minute and need for rescue analgesia at 20th minute will be recorded and the difference between these values will be evaluated by statistical methods

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122225660N1**

Registration date: **2016-02-28, 1394/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-28, 1394/12/09

Registrant information

Name

Ramin Parvizrad

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences, Arak, Iran

Expected recruitment start date

2014-05-01, 1393/02/11

Expected recruitment end date

2014-12-30, 1393/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

analgesic effect of intravenous ketamine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with isolated trauma with fracture in the upper or lower extremities; aged between 15 and 55 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, 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; any inability to express their pain during the study; presence of other trauma.

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **606**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Drugs were labeled by a study investigator as A or B in prefilled syringes in which both drug diluted until 0.1 milliliter of each syringe serve desired dose of the agent. We used 0.1 mg/kg dosage for morphine and 0.25 mg/kg for ketamine group. The eligible patients will be simply randomized in two treatment groups by using of randomized numbers table. The medication was administered by intravenous infusion during 5 minutes by registered treating nurse in a blinded fashion

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shirroodi Street

City

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Postal code

Approval date

2014-02-03, 1392/11/14

Ethics committee reference number

92-157-17

Health conditions studied

1

Description of health condition studied

Upper or Lower limb fracture

ICD-10 code

T10, T12

ICD-10 code description

Fracture of upper limb, level unspecified, Fracture of lower limb, level unspecified

2

Description of health condition studied

Upper or Lower limb dislocation

ICD-10 code

T11.2, T13

ICD-10 code description

Dislocation, sprain and strain of unspecified joint and ligament of upper limb or lower limb, level unspecified

Primary outcomes

1

Description

pain severity

Timepoint

0, 5th, 10th, 20th minute

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

dizziness, nausea, burning throat, amnesia, headache,

Timepoint

Before intervention, 5, 10 and 20 minutes after intervention

Method of measurement

physical examination

2

Description

Need for rescue analgesia

Timepoint

20 minutes after intervention

Method of measurement

Visual analog scale of pain

Intervention groups

1

Description

Intervention1 (case group): In Group A, patients receive a dose of 0.25 mg / kg iv ketamine. Drugs' dose are calculated based on patient weight. Pain severity base on visual analog score (VAS) and complication such as dizziness, nausea, amnesia, headache, will be recorded

at 0th, 5th, 10th and 20th minute. In patients with VAS of pain more than 50 mm at 20th minute, 0.05 mg/kg of intravenous morphine will be administrated as rescue analgesia .

Category

Treatment - Drugs

2**Description**

Intervention2 (case group): In Group B, patients receive a dose of 0.1 mg / kg iv morphine. Drugs' dose are calculated based on patient weight. Pain severity base on visual analog score (VAS) and complication such as dizziness, nausea, pain, amnesia, headache, will be recorded at 0, 5th, 10th and 20th minute. In patients with VAS of pain more than 50 mm at 20th minute, 0.05 mg / kg of intravenous morphine will be administrated as rescue analgesia.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali-Asr Hospital

Full name of responsible person

Dr Arash Yazdan Bakhsh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiei

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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, 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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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