

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The comparison of analgesic effect of ketamine by per kg dose(0.75mg/kg) and fixed dose 50 mg on acute traumatic and non traumatic musculoskeletal pain in patient come to Emergency ward of Emam khomeini hospital

#### Protocol summary

##### Summary

The purpose of this study is comparing reduction of pain and complications of intranasal ketamine 0.75mg/kg versus fixed dose(50mg)of Ketamine in traumatic and non traumatic musculoskeletal pain. over 15 years old with acute musculoskeletal pain patients were enrolled and patients with hemodynamic instability, impaired level of consciousness, blood pressure above 180/110, increased intracranial pressure, headache, chest pain, abdominal pain were excluded. This study is a double blind randomized clinical trial and all patients with musculoskeletal pain in Emergency department of Imam Khomeini Hospital from July to March of 1391 were included. Sample size was 132 and participants were randomized into two intervention and control groups. In intervention group, divided by weight from 40 kg to 100 kg. intervention group received 0.75 mg/kg ketamine. control group received 50mg fixed dose of ketamine. We used numerical rating scale (NSR) for assessing reduction of pain every 10 minutes for one hour.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212109162N5**  
Registration date: **2014-02-03, 1392/11/14**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-03, 1392/11/14

##### Registrant information

##### Name

Amir Nejati

##### Name of organization / entity

Tehran University of Medical Sciences, Imam Khomeini Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2240

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2012-06-21, 1391/04/01

##### Expected recruitment end date

2013-02-19, 1391/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of analgesic effect of ketamine by per kg dose(0.75mg/kg) and fixed dose 50 mg on acute traumatic and non traumatic musculoskeletal pain in patient come to Emergency ward of Emam khomeini hospital

##### Public title

comparison the effect of ketamine by per kg dose and fixed dose on pain loss of traumatic and non traumatic injury

## Purpose

Treatment

## Inclusion/Exclusion criteria

structural disease of upper airway, age<15 yr, low LOC, dementia, unstable situation, patient request of analgesic, neck pain, headache, chest pain, rise in ICP, history of rise of Iop, person who take analgesic in last 24 hour, pregnant women, BP over 180/110, acute coronary disease, heart failure, ketamine sensitivity, nasal fracture & bleeding, use of opioid & analgesic in EMS or triage, recent nasopharynx and facial surgery, orbit & eye trauma, head trauma.

## Age

From **15 years** old to **85 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **132**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Deputy of Research- Tehran University of Medical Sciences

##### Street address

Keshavarz Blvd, Qods Avenue, Central Building of Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

1439633764

#### Approval date

2012-09-02, 1391/06/12

#### Ethics committee reference number

9997/210/D/90

## Health conditions studied

### 1

#### Description of health condition studied

trauma

#### ICD-10 code

S40-S49,S5

#### ICD-10 code description

Injuries to the shoulder and upper arm, Injuries to the elbow and forearm, Injuries to the wrist and hand, Injuries to the hip and thigh, Injuries to the knee and lower leg, Injuries to the knee and lower leg, Injuries to the ankle and foot,

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

10,20,30,40,60 min after injection drug

#### Method of measurement

numeric rating scale protocol

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

in control group ketamine injection 50 mg intra nasal

#### Category

Treatment - Drugs

### 2

#### Description

in intervention group injection of ketamin intranasal 0.75mg/kg

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emergency Ward of Emam Hospital

##### Full name of responsible person

Dr Sara Payami

##### Street address

Emergency Department, Imam Khomeini Hospital, Bagherkhan Street, Chamran highway

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Deputy of Research- Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akhondzadeh, Deputy of research, Medical School

**Street address**

Medical School, Poorsina Avenue, 16 Azar, Keshavarz Blvd, Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Research- Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Sara Payami

**Position**

Emergency medicine 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**

Dr Amir Nejati

**Position**

Assistant Professor, Faculty of educational group of Emergency Medicine

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## Person responsible for updating data

**Contact****Name of organization / entity**

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emergency medicine resident

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

Emergency Department, Imam Khomeini Hospital, Baqerkhan street, Tohid Square

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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*