

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

**Evaluate and compare the analgesic effect of morphine combined with different low dose of ketamine , as compared to morphine in trauma patients admitted to the emergency department with acute , moderate to severe pain.**

### Protocol summary

#### Summary

In this randomized clinical trial, the purpose is to compare the effect of adding different doses of ketamin to the morphin for analgesia. patients with extremity trauma over 18 years old whom admitted in emergency department for a limb trauma and has moderate and severe pain will be considered. they will be divided into three groups. After injection of 0.1mg / kg of morphine ,low dose of will be add to patients (0.15mg / kg and 0.3mg / kg) in the two groups and several mL of saline as placebo is administered in the third group. Pain on the Visual Analog Scale for Pain-VAS scoring system before and after administration of morphine and ketamine is calculated at regular intervals up to 3 hours. And chart notes will be relevant. Pain relief will be examined and possible complications in three groups. Finally, the effect of ketamine on morphine for pain relief and reduce complications associated with use of this drug will be compared between the three groups.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2016030626927N1**

Registration date: **2016-06-09, 1395/03/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2016-06-09, 1395/03/20

#### Registrant information

**Name**

Mohammad Baghaei

#### Name of organization / entity

Iran university

#### Country

Iran (Islamic Republic of)

#### Phone

+98 21 8899 5017

#### Email address

dr.baghaei.m@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice President of Research IN Iran University of Medical Sciences

#### Expected recruitment start date

2015-12-22, 1394/10/01

#### Expected recruitment end date

2016-04-18, 1395/01/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluate and compare the analgesic effect of morphine combined with different low dose of ketamine , as compared to morphine in trauma patients admitted to the emergency department with acute , moderate to severe pain.

#### Public title

Evaluate and compare the analgesic effect of morphine combined with different low dose of ketamine , as compared to morphine in trauma patients admitted to the emergency department with acute , moderate to

severe pain.

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: LIMB TRAUMA;PAIN SCORE>5 ;AGE between 18-65 ; no Underlying disease ; No history of drug allergy ; No history of addiction; Exclusion criteria: Lack of cooperation or consent of the patient during the study

#### **Age**

From **18 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **180**

#### **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**

Iran University of Medical Sciences, Research Ethics Committee

###### **Street address**

hemmat highway beside the Milad tower Iran  
University of Medical Sciences

###### **City**

tehran

###### **Postal code**

##### **Approval date**

2015-12-08, 1394/09/17

##### **Ethics committee reference number**

ir.iums.rec.1394.9211307032

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

UPPER limb injury

##### **ICD-10 code**

T10

##### **ICD-10 code description**

Fracture of upper limb, level unspecified

#### 2

##### **Description of health condition studied**

injuries of upper limb, level unspecified

##### **ICD-10 code**

t11

##### **ICD-10 code description**

Other injuries of upper limb, level unspecified

#### 3

##### **Description of health condition studied**

Other injuries of lower limb, level unspecified

##### **ICD-10 code**

t13

##### **ICD-10 code description**

Other injuries of lower limb, level unspecified

#### 4

##### **Description of health condition studied**

Fracture of lower limb, level unspecified

##### **ICD-10 code**

T12

##### **ICD-10 code description**

Fracture of lower limb, level unspecified

### **Primary outcomes**

#### 1

##### **Description**

pulse rate

##### **Timepoint**

At the indicated times after injection: minutes 0 15 30 60  
90 120 150 180

##### **Method of measurement**

counting

#### 2

##### **Description**

respiratory rate

##### **Timepoint**

At the indicated times after injection: minutes 0 15 30 60  
90 120 150 180

##### **Method of measurement**

counting

#### 3

##### **Description**

pain

##### **Timepoint**

At the indicated times after injection: minutes 0 15 30 60  
90 120 150 180

##### **Method of measurement**

visual scale assessment

#### 4

**Description**

blood pressure

**Timepoint**

At the indicated times after injection: minutes 0 15 30 60  
90 120 150 180

**Method of measurement**

manometer

#### 5

**Description**

o2 saturation

**Timepoint**

At the indicated times after injection: minutes 0 15 30 60  
90 120 150 180

**Method of measurement**

pulse oxymetry

### Secondary outcomes

#### 1

**Description**

nausea

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

#### 2

**Description**

vomitting

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

#### 3

**Description**

apnea

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

#### 4

**Description**

hypoventiation

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

#### 5

**Description**

aspiration

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

#### 6

**Description**

confusion

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

#### 7

**Description**

dysphria

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

#### 8

**Description**

drug reaction

**Timepoint**

To 3 hours after injection.

**Method of measurement**

patient warning

### Intervention groups

#### 1

**Description**

Injection of 0.1mg / kg of morphine with a few ml of distilled water in separate syringes in the control group

**Category**

Treatment - Drugs

#### 2

**Description**

Injection of 0.1mg / kg morphine with low doses of ketamine in the intervention group

**Category**

Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Shohadaye hafte tir hospital

**Full name of responsible person**

Mohammad Baghaei

**Street address**

Rajai highway

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

Firuzgar hospital

**Full name of responsible person**

Mohammad Baghaei

**Street address**

Firooz alley Valiasr square

**City**

Tehran

**3**

**Recruitment center**

**Name of recruitment center**

Rasool Akram hospital

**Full name of responsible person**

Mohammad Baghaei

**Street address**

Sattarkhan street

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice President of Research IN Iran University of Medical Sciences

**Full name of responsible person**

Mrs Irani

**Street address**

Hemmat highway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice President of Research IN Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammad Baghaei

**Position**

resident

**Other areas of specialty/work**

**Street address**

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**Person responsible for scientific inquiries**

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**Full name of responsible person**

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**Contact**

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**Email**

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*