

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of different doses of paracetamol with ketamine in reducing pain in limb trauma patients in the prehospital environment

#### Protocol summary

##### Study aim

Determining the effect of paracetamol in comparison with ketamine on reducing pain in limb trauma patients in pre-hospital environment

##### Design

Clinical trial with four groups of parallel, double-blind, randomized, phase 3 on 1200 patients. Due to the fact that it is not possible to blind the technicians in a station for the type of intervention, randomization will be done for the station.

##### Settings and conduct

This study is a double-blind clinical trial that will be performed in the pre-hospital emergency system of Tehran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 70 years with limb trauma, Patients with acute limb trauma, weight between 50 to 115 kg, systolic blood pressure over than 90 mm Hg and visual Analogue scale over than 3.

Exclusion criteria: History of drug abuse, known allergy to ketamine and acetaminophen, alcohol abuse and overdose, history of liver problems, history of seizures, GCS less than 14, multiple trauma patient, instability of vital signs, pregnant, lactating, blood pressure above 110/180

##### Intervention groups

3 emergency stations IM ketamine injection 3 emergency stations IV ketamine injection 3 emergency stations acetaminophen with dose of 1 gram 3 emergency stations acetaminophen with dose of 2 gram

##### Main outcome variables

Pulse rate; Number of breaths; Systolic and diastolic blood pressure; Oxygen saturation; GCS; Visual Analogue scale; Age; Gender; Type of injury; Duration of the intervention until delivery to the hospital

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210214050351N1**  
Registration date: **2021-04-01, 1400/01/12**  
Registration timing: **prospective**

Last update: **2021-04-01, 1400/01/12**

Update count: **0**

##### Registration date

2021-04-01, 1400/01/12

##### Registrant information

##### Name

Mojgan Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2316

##### Email address

dr.mojganrahimii@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2022-04-21, 1401/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of different doses of paracetamol with ketamine in reducing pain in limb trauma patients in the prehospital environment

**Public title**

Comparison of the effect of different doses of paracetamol with ketamine

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with acute limb trauma Weight between 50-115 kg Systolic blood pressure over than 90 mm Hg Visual Pain Scale over than 3

**Exclusion criteria:**

History of drug abuse Known allergy to ketamine and acetaminophen Alcohol and psychedelics History of liver problems History of seizures GCS less than 14 Multiple trauma patient Instability of vital signs History of cardiac ischemia Pregnant Breastfeeding Blood pressure more than 110/180

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **1200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Due to the fact that individual randomization is not possible for patients as well as blinding technicians in an emergency stations for the type of intervention, randomization will be done in a cluster unit and for the emergency stations. In this method, 12 emergency stations are selected from the emergency stations of Tehran Emergency Center and randomization study will be performed for 4 arms by block randomization method and using Stata v14 software. In such a way that after preparing a list of 12 emergency stations and assigning codes 1 to 4 for each of the study arms, 3 emergency stations randomization for IM ketamine injection, 3 emergency stations IV ketamine injection, 3 emergency stations acetaminophen with dose of 1 gram and 3 emergency stations for acetaminophen with dose of 2 grams. In each of the station will inject the same drug given for all patients that specialized with the conditions of admission to the study. All site technicians will be kept unaware of the type of intervention that is taking place at other stations. Sampling in the station will continue until reaching 300 people in each group (specified sample size).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Due to the fact that it is not possible to blind the technicians in a database for the type of intervention, cluster randomization will be done for the database and so blinding will also be done at the emergency stations

level. So that the technicians of each emergency stations participating in the study will be kept unaware of the type of intervention of the other emergency stations and they will not be informed which other emergency stations participate in this study and what kind of intervention and medication they use.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of medical faculty of Tehran University of Medical Science

**Street address**

Imam Khomeini Hospital Complex, Dr Gharib St., Khashavarz Blvd., Tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1419733133

**Approval date**

2021-01-30, 1399/11/11

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1399.1029

**Health conditions studied****1****Description of health condition studied**

Limb trauma

**ICD-10 code**

G89.11

**ICD-10 code description**

Acute pain due to trauma

**Primary outcomes****1****Description**

Pulse rate

**Timepoint**

Measurement of pulse rate in at least 3 time intervals before the intervention, 15 and 30 minutes after the intervention and at the time of delivery to the hospital

**Method of measurement**

pulseoxymeter

## 2

### **Description**

respiratory rate

### **Timepoint**

Measure the number of breath in at least 3 time intervals before the intervention, 15 and 30 minutes after the intervention and at the time of delivery to the hospital

### **Method of measurement**

inspected respiratory rate in one minute

## 3

### **Description**

Systolic and diastolic blood pressure

### **Timepoint**

Measurement of systolic and diastolic blood pressure in at least 3 time intervals before the intervention, 15 and 30 minutes after the intervention and at the time of delivery to the hospital

### **Method of measurement**

blood pressure cuff

## 4

### **Description**

Oxygen saturation rate

### **Timepoint**

Measurement of oxygen saturation in at least 3 time intervals before the intervention, 15 and 30 minutes after the intervention and at the time of delivery to the hospital

### **Method of measurement**

pulseoxymeter

## 5

### **Description**

Glasgow Coma Scale

### **Timepoint**

Measurement of Glasgow Coma Scale at least 3 time intervals before intervention, 15 and 30 minutes after intervention and at the time of hospital delivery

### **Method of measurement**

Patient examination

## 6

### **Description**

Visual Analogue scale

### **Timepoint**

Measurement of visual Analogue scale in at least 3 time intervals before the intervention, 15 and 30 minutes after the intervention and at the time of delivery to the hospital

### **Method of measurement**

ask the patient

## 7

### **Description**

age

### **Timepoint**

at the beginning

## **Method of measurement**

ask the patient

## 8

### **Description**

sex

### **Timepoint**

at the beginning

### **Method of measurement**

inspection

## 9

### **Description**

type of injury

### **Timepoint**

at the beginning

### **Method of measurement**

patient examination

## 10

### **Description**

time duration from intervention till to reaching hospital

### **Timepoint**

at the end of reaching hospital

### **Method of measurement**

duration per hour

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: IM ketamine injection, 3 mg per kg body weight, once, if needed and no pain relief 30 mg intravenous Ketorolac, Manufacturer: Sina Pakhsh Saba

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: IV ketamine injection, 0.5 mg per kg body weight for 2-3 minutes, once, if needed and no pain relief 30 mg intravenous Ketorolac, Manufacturer: Sina Pakhsh Saba

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group 3: Acetaminophen at a dose of 2 g dissolved in 100 cc of normal saline for 15 minutes, once, if needed and without pain relief 30 mg intravenous ketorolac, manufacturer: Exir Pharmacy

#### **Category**

Treatment - Drugs

#### 4

##### **Description**

Control group: Acetaminophen at a dose of 1 g dissolved in 100 cc of normal saline for 15 minutes, once, if needed and without pain relief 30 mg intravenous ketorolac, manufacturer: Exir Pharmacy

##### **Category**

Treatment - Drugs

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Emergency station

###### **Full name of responsible person**

Mojgan Rahimi

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

Imam Khomeini Hospital Complex, Qarib St.,  
Keshavarz Blvd.

###### **City**

Tehran

###### **Province**

Tehran

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

1419733133

###### **Phone**

+98 21 6119 2317

###### **Email**

dr.mojganrahimii@gmail.com

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Tehran emergency center

###### **Full name of responsible person**

Peyman Saberian

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

Sharif, Iranshahr

###### **City**

Tehran

###### **Province**

Tehran

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

1581615117

###### **Phone**

+98 21 4923 1000

###### **Email**

peymansaberian61@gmail.com

###### **Grant name**

###### **Grant code / Reference number**

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

Yes

###### **Title of funding source**

Tehran emergency center

###### **Proportion provided by this source**

50

###### **Public or private sector**

Public

###### **Domestic or foreign origin**

Domestic

###### **Category of foreign source of funding**

*empty*

###### **Country of origin**

###### **Type of organization providing the funding**

Other

#### 2

##### **Sponsor**

###### **Name of organization / entity**

Tehran University of Medical Sciences

###### **Full name of responsible person**

Mohammad Ali Sahraian

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

Tehran University of Medical Science, qods St.,  
Keshavarz Blvd.

###### **City**

Tehran

###### **Province**

Tehran

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

1417613151

###### **Phone**

+98 21 6670 6142

###### **Email**

msahrai@tums.ac.ir

###### **Grant name**

###### **Grant code / Reference number**

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

Yes

###### **Title of funding source**

Tehran University of Medical Sciences

###### **Proportion provided by this source**

50

###### **Public or private sector**

Public

###### **Domestic or foreign origin**

Domestic

###### **Category of foreign source of funding**

*empty*

###### **Country of origin**

###### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

##### **Contact**

###### **Name of organization / entity**

Tehran University of Medical Sciences

###### **Full name of responsible person**

Mojgan Rahimi

###### **Position**

Associate Professor

###### **Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Khomeini Hospital Complex, Dr Gharib St.,  
Keshavarz Blvd., Tehran Keshavarz

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mojgan Rahimi

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mojgan Rahimi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Sharing plan**

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available