

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of Sub-dissociative dose of ketamine and morphine sulfate for acute pain control of patients with isolated limb injuries in the emergency department

#### Protocol summary

##### Study aim

Comparison of sub-dissociative dose of ketamine and morphine sulfate for acute pain control of patients with isolated limb injuries in the emergency department

##### Design

Phase 3 triple blinded randomized clinical trial with parallel groups. Sample size: 70 patients.

##### Settings and conduct

This study will be conducted in Imam Khomeini Hospital in Tehran, Iran, which is an academic hospital. This will be a triple blinded randomized clinical trial. The emergency department sees 70000 patients annually. Patients, the committee that monitors the response variable, and the analyzer will be blinded. All randomizations and drug preparations will be done by a single investigator who will not participate in patients enrollment, assessment, and analysis. Patients with isolated limb trauma who has pain intensity equal to or greater than 5 of 11 on NRS will receive intravenous morphine or ketamine randomly.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Emergency department patients with isolated traumatic limb injuries with a pain score of 5 or more on a standard 11-point (0-10) numerical rating scale. Exclusion criteria: Patients with altered mental status, Patients with unstable vital signs, Patients with known underlying hepatic or renal diseases, Pregnant patients, Non-consent patients, and Patients under the age of 18 or over the age of 55 years old

##### Intervention groups

The first intervention group: 0.1 mg/kg ketamine in 10 mL normal saline over 5 minutes intravenously. The second intervention group: 0.05 mg/kg morphine in 10 mL normal saline over 5 minutes intravenously.

##### Main outcome variables

Pain intensity; adverse events.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150213021063N6**

Registration date: **2020-07-20, 1399/04/30**

Registration timing: **retrospective**

Last update: **2020-07-20, 1399/04/30**

Update count: **0**

##### Registration date

2020-07-20, 1399/04/30

##### Registrant information

##### Name

Arash Safaie

##### Name of organization / entity

Tehran University of Medical Sciences- Sina Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 216312413

##### Email address

a-safaie@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2017-01-20, 1395/11/01

##### Actual recruitment start date

2016-01-21, 1394/11/01

##### Actual recruitment end date

2017-01-20, 1395/11/01

##### Trial completion date

2017-01-20, 1395/11/01

### Scientific title

Comparison of Sub-dissociative dose of ketamine and morphine sulfate for acute pain control of patients with isolated limb injuries in the emergency department

### Public title

Ketamine versus morphine for acute pain control

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Emergency department patients with isolated traumatic limb injuries with a pain score of 5 or more on a standard 11-point (0-10) numerical rating scale

#### Exclusion criteria:

Patients with altered mental status Patients with unstable vital signs Patients with known underlying hepatic or renal diseases Pregnant patients Non-consent patients Patients under the age of 18 or over the age of 55 years old

### Age

From **18 years** old to **55 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **70**

Actual sample size reached: **73**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block randomization will be performed using random numbers table. The random numbers table itself will be made by the <http://random.org> website. The drugs will be prepared in blocks of similar looking 10 mL syringes allocated to the 2 intervention groups.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

All randomizations and drug preparations will be done by a single investigator who will not participate in patients enrollment, assessment, and analysis. The other investigators and patients will be blinded. Also the committee that monitor response variable will be blinded.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of Tehran University of Medical Sciences

##### Street address

Building No 1- Northern gate of the university- Poursina street- Qods street- Enghelab avenue.

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733151

#### Approval date

2016-01-20, 1394/10/30

#### Ethics committee reference number

IR.TUMS.REC.1394.1710

## Health conditions studied

### 1

#### Description of health condition studied

Acute pain due to trauma

#### ICD-10 code

G89.11

#### ICD-10 code description

Acute pain due to trauma

## Primary outcomes

### 1

#### Description

Pain intensity

#### Timepoint

Before drug administration, 5, 10, 15, 20, 25, and 30 minutes after drug administration

#### Method of measurement

Numeric rating scale

## Secondary outcomes

### 1

#### Description

Adverse events

#### Timepoint

Patients will be monitored continuously for adverse events since drug administration till patient discharge.

#### Method of measurement

Specific occurred adverse event

## Intervention groups

### 1

#### Description

Intervention group: 0.1 mg/kg ketamine in 10 mL normal saline over 5 minutes intravenously

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: 0.05 mg/kg morphine in 10 ml normal saline over 5 minutes intravenously

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Dr. Seyed Mojtaba Aghili

##### Street address

Chamran Highway, Baqerkhan Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6119 0000

##### Email

Imamhospital@tums.ac.ir

##### Web page address

<http://ikhc.tums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Ali Sahraian

##### Street address

Building No 1- Northern gate of the university- Poursina street- Qods street- Enghelab avenue.

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733151

##### Phone

+98 21 6641 8466

#### Email

msahrai@sina.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

100

#### 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

Dr. Seyed Mojtaba Aghili

##### Position

Assistant professor of emergency medicine

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

##### Street address

Emergency Department, Imam Khomeini Hospital, Baqerkhan Street, Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6690 4848

##### Email

aghili220@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Seyed Mojtaba Aghili

##### Position

Assistant professor of emergency medicine

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

**Street address**

Emergency Department, Imam Khomeini Hospital,  
Baqerkhan Street, Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6690 4848

**Email**

aghili220@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Arash Safaie

**Position**

Assistant professor of emergency medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Emergency Department, Sina Hospital, Hassan Abad  
square.

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 1413

**Fax****Email**

a-safaie@sina.tums.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All unidentified IPD and statistical analyses are sharable.

**When the data will become available and for how long**

شروع دوره دسترسی 1 ماه پس از چاپ

**To whom data/document is available**

Data will be available for academic, scientific, or  
industrial institutes researchers.

**Under which criteria data/document could be used**

Data will be shared upon Written request of the  
individual researcher or the institute.

**From where data/document is obtainable**

Data will be shared by sending email to Arash Safaie.  
Email: aghili220@yahoo.com

**What processes are involved for a request to access data/document**

Data will be shared by sending email to Dr. Seyed  
Mojtaba Aghili. We will try our best to send you the  
requested data as soon as possible.

**Comments**