

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Evaluation of the effect of intravenous Ketamine in reducing postoperative pain in lower limb fracture

#### Protocol summary

##### Study aim

Controlling pain and its complications and reducing the use of narcotic painkillers after surgery

##### Design

In this study, 88 patients are randomly assigned to two groups, case and control.

##### Settings and conduct

In this double-blind clinical trial study, all patients who undergo orthopedic surgery at Shahid Beheshti Hospital in Babol are included in the study.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: age 20 to 60 years old; lower limb fracture; having consent to enter the study. Exclusion criteria: patients with a history of psychosis and cognitive disorders; patients with a history of drug addiction; pregnant women.

##### Intervention groups

The case group will receive 0.3 mg/kg (ketamine) half an hour before induction of anesthesia as an intravenous injection, and the control group will receive intravenous infusion of normal saline, as a placebo, in a volume equal to ketamine.

##### Main outcome variables

Pain; Nausea; Vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221029056333N1**

Registration date: **2022-11-02, 1401/08/11**

Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**

Update count: **0**

##### Registration date

2022-11-02, 1401/08/11

#### Registrant information

##### Name

Mehdi Tavasoli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3225 6285

##### Email address

m.tavasoli@mubabol.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2022-11-16, 1401/08/25

##### Expected recruitment end date

2022-12-16, 1401/09/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Evaluation of the effect of intravenous Ketamine in reducing postoperative pain in lower limb fracture

#### Public title

Effect of intravenous Ketamine in reducing postoperative pain

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 20 to 60 years old Lower limb fracture Having consent to enter the study

##### Exclusion criteria:

Patients with a history of psychosis and cognitive disorders Patients with a history of drug addiction

Pregnant women

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **88**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Permuted randomization block is used. Other blocks are considered 4. In each block, the ratio of ketamine and placebo is equal (1:1). The creation of a random order in each block is done by a statistician.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Drug injection will be done by an anesthesiologist. The patients and the evaluator (orthopedic resident) are not aware of the title of the text of the drug type.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Babol University of Medical Sciences

**Street address**  
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

**City**  
Babol

**Province**  
Mazandaran

**Postal code**  
4716681451

**Approval date**  
2022-10-17, 1401/07/25

**Ethics committee reference number**  
IR.MUBABOL.REC.1401.106

## Health conditions studied

### 1

**Description of health condition studied**  
Lower limb fracture

**ICD-10 code**  
T12

**ICD-10 code description**  
Lower limb fracture

## Primary outcomes

### 1

**Description**  
Pain

**Timepoint**  
In 5 recovery periods, 6 hours, 12 hours and 24 hours after surgery

**Method of measurement**  
Using the VAS scale & record severe pain intensity

## Secondary outcomes

### 1

**Description**  
Nausea

**Timepoint**  
24 hours after surgery

**Method of measurement**  
By N&V benchmark

### 2

**Description**  
Vomiting

**Timepoint**  
24 hours after surgery

**Method of measurement**  
By N&V benchmark

## Intervention groups

### 1

**Description**  
Intervention group: 0.3 mg/kg (ketamine) is given as an intravenous injection half an hour before induction of anesthesia.

**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: They will receive an intravenous infusion of normal saline, as a placebo, in a volume equal to that of ketamine.

**Category**  
Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr. Mehdi Tavasoli

**Street address**

Babol University of Medical Sciences, Ganjafrouz  
Street, Babol, Mazandaran, Iran

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**Web page address**

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Rajabnia

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Street, Babol, Mazandaran, Iran

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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**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Meysam Mahmodi

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Babol University of Medical Sciences

**Full name of responsible person**  
Dr. Mehdi Tavasoli

**Position**  
Assistant professor

**Latest degree**  
Specialist

**Other areas of specialty/work**  
Orthopedics

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

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### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available