Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

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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

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Sponsors / Funding sources

1

Sponsor

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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

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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
.
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