

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of various dosages of Ketamin on postoperative pain in opiate-dependent patients undergoing radius distal, femur, and tibia fracture orthopedic surgery

#### Protocol summary

##### Study aim

Investigating the effectiveness of different doses of ketamine on postoperative pain in drug addicts undergoing orthopedic surgery for fractures of the distal radius, femur, and tibia

##### Design

A clinical trial with a control group, with parallel groups, 1 blind, randomized, phase 0 on 50 patients. The rand function of Excel software was used for randomization

##### Settings and conduct

Patients with a history of drug abuse, aged 18-65 years old, were referred to Shahid Beheshti Hospital in Kashan in 1401 for orthopedic surgery due to distal radius trauma of the upper limb and fractures of the femur and tibia of the lower limb.

##### Participants/Inclusion and exclusion criteria

Patients with a history of drug abuse aged 18-65 (18 to 65 years were chosen to minimize the possibility of age-related mood disorders) are the age to undergo orthopedic surgery due to trauma to the distal radius of the upper limb and bone fracture. The lower limb femur and tibia were referred to Shahid Beheshti Hospital in Kashan in 1401. Exclusion criteria: Patients with multiple traumas, consumption of alcohol, and artificial drugs not derived from opium Patients who continuously use drugs other than narcotics The patient's lack of consent for the study or the patient's lack of cooperation after entering the study History of seizures or drug sensitivity to ketamine and other contraindications to ketamine History of cardiovascular diseases

##### Intervention groups

First group ketamine 1 mg/kg The second group received 0.5 mg/kg in the third group, normal saline as a placebo at the beginning of the surgical incision.

##### Main outcome variables

pain intensity score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230804059031N1**

Registration date: **2023-11-26, 1402/09/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-11-26, 1402/09/05**

Update count: **0**

##### Registration date

2023-11-26, 1402/09/05

##### Registrant information

##### Name

Ali Khandan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 163 2580

##### Email address

khandan.dr@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-05, 1402/08/14

##### Expected recruitment end date

2023-12-05, 1402/09/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Effect of various dosages of Ketamin on postoperative pain in opiate-dependent patients undergoing radius distal, femur, and tibia fracture orthopedic surgery

## Public title

The Effect of Various dosage of Ketamin on postoperative pain in opiate-dependent patients undergoing orthopedic surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with a history of drug abuse 18-65 years

### Exclusion criteria:

Patients with multiple trauma Consumption of alcohol and artificial drugs not derived from opium Patients should have continuous use of drugs other than narcotics Lack of patient consent for the study Non-cooperation of the patient after entering the study History of seizures or drug sensitivity to ketamine and other contraindications to ketamine History of cardiovascular diseases

## Age

From **18 years** old to **6 years** old

## Gender

Both

## Phase

0

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The method of assigning people will be the "Permuted Block Randomization" method. In this way, gradually and in the order of referral for surgery, for all three patients who will be referred, in advance by randomly selecting one of the following blocks using the table of random numbers (numbers 1 to 6) the desired sequence for the block of three The next three patients will be selected. sequence of blocks and corresponding numbers; 1) ABC 2) ACB 3) BAC 4) BCA 5) CAB 6) CBA A, 1mg/kg ketamine, B, 0.5 mg/kg ketamine C, normal saline A total of about 24 sequences will be selected.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

کارگروه/ کمیته اخلاق در پژوهش دانشکده پزشکی و دندانپزشکی-  
دانشگاه علوم پزشکی کاشان

##### Street address

56 Hekmat, Qutub Rawandi Boulevard, Kashan,  
Isfahan Province

##### City

Kashan

##### Province

Isfahan

##### Postal code

81151-87159

#### Approval date

2022-08-21, 1401/05/30

#### Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.089

## Health conditions studied

### 1

#### Description of health condition studied

Upper and lower limb fractures

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Investigating the effectiveness of different doses of ketamine on postoperative pain in drug addicts undergoing orthopedic surgery for fractures of the distal radius, femur and tibia.

#### Timepoint

2, 6, 12 and 25 hours after the operation

#### Method of measurement

1 to 10

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: 1mg/kg/  
ketamine/C13H16ClNO/intravenous and at the beginning  
of surgical incision/1 shift/made by Rotex Germany  
company/

#### Category

Treatment - Drugs

## 2

### Description

Intervention group 2: 0.5 mg/Ketamine/C13H16ClNO/kg/intravenous and at the beginning of surgical incision/1 shift/made by German Rotex company

### Category

Treatment - Drugs

## 3

### Description

Intervention group3: normal saline/SODIUM CHLORIDE 0.9percent /intravenous and at the beginning of surgical incision/1 turn/manufactured by Iran Injectable and Pharmaceutical Products Company

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

بیمارستان شهید بهشتی

##### Full name of responsible person

Ali Khandan

##### Street address

استان اصفهان، کاشان، بلوار علامه قطب راوندی

##### City

Kashan

##### Province

Isfahan

##### Postal code

81151/87159

##### Phone

+98 31 5554 0026

##### Email

khandan.dr@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Gholam Ali Hamidi

##### Street address

Kashan - Qutb Rawandi Boulevard - Kashan University of Medical Sciences

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715981151

##### Phone

+98 31 5558 9007

### Email

hamiidi@yahoo.com

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

Kashan 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

Kashan University of Medical Sciences

#### Full name of responsible person

Ali Khandan

#### Position

Anesthesiology resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Anesthesiology

#### Street address

بلوار امام رضا ، نبش بلوار، جنب سوپر پروتئین کاشان

#### City

Kashan

#### Province

Isfahan

#### Postal code

87159-81151

#### Phone

+98 913 163 2580

#### Fax

#### Email

khandan.dr@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Ali Khandan

#### Position

Anesthesiology resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Anesthesiology

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**Fax****Email**

khandan.dr@gmail.com

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

Yes - There is a plan to make this available

**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

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

Only a part of the data, such as the information related to the main result or the like, can be shared.

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

The access period starts 6 months after the results are published

**To whom data/document is available**

It will be available only to researchers working in academic and scientific institutions

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

There are no other conditions for the use of data or documentation

**From where data/document is obtainable**

Ali Khandan

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

After the initial review of the request, it will be sent to them within a month

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

Kashan University of Medical Sciences

**Full name of responsible person**

Ali Khandan

**Position**

Anesthesiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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