

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

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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

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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

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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

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Fax**Email**

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Email

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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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