

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effects of ketamine and pethidine on pain control after surgery in upper and lower limbs orthopedic surgery candidates

#### Protocol summary

##### Study aim

Comparison of the effect of ketamine and pethidine on pain control after orthopedic surgery

##### Design

The randomized double-blind controlled clinical trial, phase 3 on 80 patients. ralloc package in stata was used for randomization

##### Settings and conduct

After selecting the participants from Imam Khomeini Hospital, the patients will be divided into two groups with a random block approach. In the end, the pain score will be measured by considering blinding.

##### Participants/Inclusion and exclusion criteria

Inclusion: candidate for elective orthopedic surgery with general anesthesia and class I and II in the ASA classification 18 to 60 yrs old No history of opioid addiction Absence of underlying diseases such as liver and kidney failure, history of seizures, pregnancy, and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease, and history of disease respiratory No history of drug sensitivity to pethidine or ketamine  
Exclusion: opioid addiction underlying diseases such as liver and kidney failure, history of seizures, pregnancy and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease, and history of disease respiratory mental retardation or psychological illness drug sensitivity to pethidine or ketamine chronic use of painkillers

##### Intervention groups

In the intervention group, Patients will receive ketamine at a dose of 0.3mg/kg 30 minutes after induction of anesthesia. for the control group, Patients will not receive any other drug during anesthesia. After the surgery, when the extubating conditions are suitable, the patient's tracheal tube will be removed and after regaining consciousness, they will receive this medicine at the same dose of 1mg/kg slowly and intravenously.

##### Main outcome variables

Pain score in two group

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230228057570N1**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **prospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

##### Registration date

2023-07-12, 1402/04/21

##### Registrant information

##### Name

Hamed Azadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 84 3323 4725

##### Email address

azadi\_eyvan\_2012@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effects of ketamine and pethidine on pain control after surgery in upper and lower limbs orthopedic surgery candidates

### Public title

Comparison of the effect of ketamine and pethidine on pain control

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

candidate for elective orthopedic surgery with general anesthesia and class I and II in the ASA classification Age range from 18 to 60 years No history of opioid addiction Absence of underlying diseases such as: liver and kidney failure, history of seizures, pregnancy and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease and history of disease respiratory No history of disorders such as mental retardation or psychological illness No history of drug sensitivity to pethidine or ketamine No history of chronic use of painkillers

#### Exclusion criteria:

opioid addiction underlying diseases such as: liver and kidney failure, history of seizures, pregnancy and breastfeeding, high ICP (intracranial pressure) and glaucoma, thyrotoxicosis, high blood pressure, diabetes, heart disease and history of disease respiratory mental retardation or psychological illness drug sensitivity to pethidine or ketamine chronic use of painkillers

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Balance block randomization method will be used for random allocation of participants. for that, 6 blocks with 4 permutations will be created in the following order 1=KKPP 2=KPKP 3=KPPK 4=PKPK 5=PPKK 6=PKKP where P represents pethidine group and K represents ketamine group. Then, based on the numbers in the random table, a number will be chosen randomly, and based on the last digit on the right, one of the groups will be used to determine the sequence of randomization. It should be noted that if the number on the right side is zero or 7 to 9 when choosing a random number, that number will not be considered and a random number will be selected again. This process, will continue until all 80 participants are assigned to two groups. It should be noted that this

method will prevent the unbalance of the two groups as well as the identification of the randomization sequence.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

For blinding, each drug will be assigned a code that can only be identified by the principal investigator and neither the patient nor the person who is collecting data will unknow what drug the patient has taken. For this purpose, the same cover and appearance of the medicine vials will be prepared.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ilam University of Medical Sciences

##### Street address

Ilam University of Medical Sciences campus, Banganjab, Pazhohesh Blvd

##### City

Ilam

##### Province

Ilam

##### Postal code

6939177143

#### Approval date

2023-06-18, 1402/03/28

#### Ethics committee reference number

IR.MEDILAM.REC.1402.060

## Health conditions studied

### 1

#### Description of health condition studied

Fracture of upper limb

#### ICD-10 code

T10

#### ICD-10 code description

Fracture of upper limb, level unspecified

### 2

#### Description of health condition studied

Fracture of lower limb

#### ICD-10 code

S82

#### ICD-10 code description

Fracture of lower leg, including ankle

## Primary outcomes

### 1

#### Description

Pain score based on Visual Analogue Scale tool

#### Timepoint

at recovery room, 6 and 12 hours after surgery

#### Method of measurement

Visual Analogue Scale tools

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The patients in the ketamine group will receive ketamine at a dose of 0.3mg/kg 30 minutes after the induction of anesthesia. For this purpose, the patients will undergo standard monitoring (pulse oximetry, heart rate, blood pressure, and echocardiography) before surgery, and the vital signs of the patients will be evaluated and recorded every 5 minutes in the first 15 minutes. Then this process repeated every 15 minutes. Induction of anesthesia in all patients is as follows: they will be anesthetized with 2mg/kg propofol, 2ug/kg fentanyl, and 0.5mg/kg atracurium, and then the patients will undergo tracheal intubation. Anesthesia will be continued with a mixture of oxygen and nitrous oxide in equal proportions and isoflurane equivalent to MAC and continuous injection of atracurium at a dose of 0.2mg/kg.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: for patients in the pethidine group, the extubation will be done after surgery and in a suitable situation. When patients get consciousness, pethidine will be injected with the dose of 1mg/kg slowly and intravenously, then the patients will be transferred to recovery and under standard monitoring again.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Hamed Azadi

##### Street address

Haidari Street, Ilam

#### City

Ilam

#### Province

Ilam

#### Postal code

6931975397

#### Phone

+98 84 3333 4500

#### Fax

+98 84 3333 4500

#### Email

azadi\_eyvan\_2012@yahoo.com

#### Web page address

<https://emamhospital.medilam.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ilam University of Medical Sciences

##### Full name of responsible person

Dr Sobhan Ghafourian

##### Street address

ilam university of medical science

##### City

Ilam

##### Province

Ilam

##### Postal code

6931851147

##### Phone

+98 84 3333 4060

##### Fax

+98 84 3333 4060

##### Email

azadi\_eyvan\_2012@yahoo.com

##### Web page address

<https://www.medilam.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ilam 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**

Ilam University of Medical Sciences

**Full name of responsible person**

Hamed Azadi

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

**Street address**

Haidari street, Ilam

**City**

Ilam

**Province**

Ilam

**Postal code**

6931975397

**Phone**

+98 84 3333 4500

**Fax**

+98 84 3333 4500

**Email**

azadi\_eyvan\_2012@yahoo.com

rezapakzad2010@yahoo.com

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

Ilam University of Medical Sciences

**Full name of responsible person**

Hamed Azadi

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ilam University of Medical Sciences campus,  
Banganjab, Research Blvd

**City**

Ilam

**Province**

Ilam

**Postal code**

6931851147

**Phone**

+98 84 3333 4060

**Fax**

+98 84 3333 4060

**Email**

azadi\_eyvan\_2012@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

Reza Pakzad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

Ilam University of Medical Sciences campus,  
Banganjab, Research Blvd

**City**

Ilam

**Province**

Ilam

**Postal code**

6939177143

**Phone**

+98 84 3222 7134

**Fax**

+98 84 3222 7134

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available