# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jul 2026

## Comparison the effect of pre-operative oral memantine and placebo on pain following orthopedic surgery

## Protocol summary

**Summary**

The aim of this study is to evaluate the effect of pre-operative oral memantine on pain following orthopedic surgery in Zahedan in 2015 and 2016. This study is a double blind randomized clinical trial. 11 blocks (10 patients for each block) was used for randomization with an equal number of cards for each case and control groups based on factorial design. Both patients and the researchers who collected questionnaires from patients were not aware of the intervention type. Inclusion criteria included patients who require orthopedic surgery of the lower limbs below the knee, and exclusion criteria including dissatisfaction of patients and complications occurring in patients. In this study, 110 patients (55 patients in the intervention group and 55 patients in the control group) will be enrolled. In intervention group 20 mg of memantine was administrated and placebo was administrated to the other group one hour before surgery. Then pain severity (based on the Visual Analogue Scale) and analgesic amount was evaluated in 30 and 60 minutes, 2, 12 and 24 hours after surgery in two groups of patients.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015101824576N1**
Registration date: **2016-06-10, 1395/03/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2016-06-10, 1395/03/21

**Registrant information**

**Name**

Khalil Soloki

**Name of organization / entity**

Zahedan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Zahedan University of Medical Sciences

**Expected recruitment start date**

2015-06-22, 1394/04/01

**Expected recruitment end date**

2016-02-20, 1394/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of pre-operative oral memantine and placebo on pain following orthopedic surgery

**Public title**

Oral memantine and pain after orthopedic surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria including age range between 18 and 60 years, having indications for spinal anesthesia, having surgery of the lower limbs below the knee for bone plaque embedding. Exclusion criteria including any postoperative complication requires surgical intervention, lack of consent to participate in the study, having a history of substance abuse, history of chronic

disease such as diabetes, high blood pressure and etc. taking medication, having a mental illness, having known hypersensitivity to the ketamine drug, having mental retardation and loss of consciousness, hemodynamic disorders, bleeding disorders and anemia

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **110**

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

**Randomization description**

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

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

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

**Street address**
School of Medicine - Zahedan University of Medical Sciences - Janet Boulevard – Dr. Hesabi Square - Zahedan

**City**
Zahedan

**Postal code**
43181-98167

**Approval date**
2015-01-21, 1393/11/01

**Ethics committee reference number**
2484

## Health conditions studied

### 1

**Description of health condition studied**
Patients needing orthopedic surgery of the lower limbs below the knee

**ICD-10 code**
S80-S99

**ICD-10 code description**
Injury, poisoning and certain other consequences of external causes

## Primary outcomes

### 1

**Description**
Pain intensity

**Timepoint**
30 and 60 minutes, 2, 12 and 24 hours after surgery

**Method of measurement**
VAS (Visual Analogue Scale) ruler

## Secondary outcomes

### 1

**Description**
consumption of Analgesic amount

**Timepoint**
30 and 60 minutes, 2, 12 and 24 hours after surgery

**Method of measurement**
mg

## Intervention groups

### 1

**Description**
Intervention 1: In the intervention group 20 mg of memantine were administrated one hour before surgery for the patient.

**Category**
Treatment - Drugs

### 2

**Description**
Intervention 2: In the control group placebo were administrated (a capsule containing starch inside the shed) one hour before surgery for the patient.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Zahedan Khatamolanbia hospital

**Full name of responsible person**

**Street address**

**City**
Zahedan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice Chancellor for research of Zahedan University of Medical Sciences

**Full name of responsible person**
Houshang Rafighdost

**Street address**
School of Medicine - Zahedan University of Medical Sciences – Zahedan

**City**
Zahedan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Vice Chancellor for research of Zahedan University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
*empty*

**Domestic or foreign origin**
*empty*

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Zahedan University of Medical Sciences

**Full name of responsible person**
Khalil Souloki

**Position**
resident

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Seyed Mohamad Nasialdin Tabatabaei

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Assistant Professor

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*

**Study Protocol**
*empty*

**Statistical Analysis Plan**
*empty*

**Informed Consent Form**
*empty*

**Clinical Study Report**
*empty*

**Analytic Code**
*empty*

**Data Dictionary**
*empty*