Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
+98 54 3329 5725
Email address
solokikhalil@zaums.ac.ir

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
Street address
School of Medicine - Zahedan University of Medical Sciences - Janet Boulevard – Dr. Hesabi Square – Zahedan
City
Zahedan
Postal code
Phone
+98 54 3329 5796
Fax
Email
solokikhalil@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Seyed Mohamad Nasialdin Tabatabaei
Position
Assistant Professor
Other areas of specialty/work
Street address
School of Medicine - Zahedan University of Medical Sciences - Janet Boulevard – Dr. Hesabi Square – Zahedan
City
Zahedan
Postal code
Phone
+98 54 3329 5796
Fax
Email
Ar_dashipoor@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
khalil souloki
Position
resident
Other areas of specialty/work
Street address
School of Medicine - Zahedan University of Medical Sciences - Janet Boulevard – Dr. Hesabi Square – Zahedan
City
Zahedan
Postal code
Phone
+98 54 3329 5796
Fax
Email
solokikhalil@yahoo.com
Web page address

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