

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of memantine versus placebo on pain in patients undergoing knee joint surgery: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of memantine versus placebo on pain in patients undergoing knee joint surgery

Design

This is a Phase III double-blind randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct

This study will be conducted at the Rasool Akram Hospital in Tehran city, involving 42 eligible patients undergoing knee joint surgery. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 70 years Candidate for knee joint surgery Physical health class 1 or 2 Exclusion criteria: Chronic heart disease Psychiatric diseases Alzheimer's disease Drug or alcohol addiction

Intervention groups

Intervention group: Routine treatment plus memantine tablets 20 mg daily three days before surgery and then 10 mg daily after surgery for 2 weeks Control group: Routine treatment plus a placebo pill daily three days before surgery and then a placebo pill daily after surgery for 2 weeks

Main outcome variables

Primary outcome: Pain score, pain quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N491**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

Registration date

2023-12-02, 1402/09/11

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of memantine versus placebo on pain in patients undergoing knee joint surgery: a double-blind randomized clinical trial

Public title

Effect of memantine versus placebo on pain in patients undergoing knee joint surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 70 years Candidate for knee joint surgery
Physical health class 1 or 2

Exclusion criteria:
Chronic heart disease Psychiatric diseases Alzheimer's disease Drug or alcohol addiction

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Medicine - Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, beside Milad Tower, Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-02-22, 1401/12/03

Ethics committee reference number

IR.IUMS.REC.1401.996

Health conditions studied

1

Description of health condition studied

knee joint disorders

ICD-10 code

M25.86

ICD-10 code description

Other specified joint disorders, knee

Primary outcomes

1

Description

Pain score

Timepoint

On the first, second, third, fourth, fifth and fourteenth days after surgery

Method of measurement

Using Visual Analog Scale (VAS)

2

Description

Pain quality

Timepoint

On the first, second, third, fourth, fifth and fourteenth days after surgery

Method of measurement

Using the McGill questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus memantine tablets 20 mg daily three days before surgery and then 10 mg daily after surgery for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus a placebo pill daily three days before surgery and then a placebo pill daily after surgery for 2 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital in Tehran city

Full name of responsible person

Dr. Azadeh Eshraghi

Street address

Rasool Akram Hospital, Sattar khan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Azadeh Eshraghi

Position

Clinical Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Full name of responsible person

Dr. Jalal Poorolajal

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Professor of Epidemiology

Latest degree

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Other areas of specialty/work

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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