

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of two drugs melatonin and gabapentin on shivering after knee surgery with spinal anesthesia

Protocol summary

Study aim

Comparison of the effects of melatonin and gabapentin on shivering after knee surgery under spinal anesthesia in patients referred to the operating room of Imam Reza Hospital in 1404.

Design

The samples are included in the study as they are available and if they meet the inclusion criteria. They are divided into two groups A and B by using white and black cards according to randomized method. Sample size: Considering the potential of those referred to the hospital operating room and the available samples, 100 samples are determined as the size, which will be studied in two groups of 51 people.

Settings and conduct

After entering the operating room of 501 AJA hospital, to perform spinal anesthesia, first they receive 10 ml/kg of preloaded Ringer's serum fluid, which is kept at 22 (8) degrees Celsius in the operating room, and then they are placed in a sitting position with a 25-gauge spinal needle and injected with 3 injections of 0.5% bupivacaine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- All patients aged 20-60 2- Patients with (II, I) ASA 3- No history of taking antidepressants with catecholamine or serotonin reuptake mechanisms (15, 16, 18) 4- Completed informed consent by the patient (after full explanation about the safety and health of the various stages of the plan and obtaining informed consent) Exclusion criteria : 1- Blood transfusion and its cold products during surgery 2- Patient or project manager's awareness of the type of medication prescribed 3- Lack of consent of the patient or companions for any reason during the implementation of the project

Intervention groups

Group A is prescribed melatonin at a dose of 5 mg and Group B is prescribed gabapentin at a dose of 100 mg as a single dose orally with 50 cc of water one hour before the procedure.

Main outcome variables

Shivering Nausea and vomiting Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110103005536N13**

Registration date: **2025-09-09, 1404/06/18**

Registration timing: **prospective**

Last update: **2025-09-09, 1404/06/18**

Update count: **0**

Registration date

2025-09-09, 1404/06/18

Registrant information

Name

Mohamadreza Rafiei

Name of organization / entity

Artesh University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 8933

Email address

mo_rafiei@armyums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-21, 1404/07/29

Expected recruitment end date

2026-05-20, 1405/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of two drugs melatonin and gabapentin on shivering after knee surgery with spinal anesthesia

Public title
Comparison of the effects of melatonin and gabapentin on shivering after knee surgery with spinal anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients that are 20-60 years old Patients with (II, I) ASA No history of taking antidepressants with catecholamine or serotonin reuptake mechanisms (15, 16, 18) Completion of informed consent by the patient (after full explanation about the safety and health of the various stages of the plan and obtaining informed consent)

Exclusion criteria:

Infusion of blood and its cold products during surgery Patient or project manager's awareness of the type of medication prescribed Dissatisfaction of the patient or companions for any reason during the implementation of the plan

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization using black and white cards.patients are divided into two intervention and control groups. since the sampling is convenience or available the first patient who visits is randomly assigned to the melatonin group(if shivering occurs) by receiving a white card and the next patient who receives a black card is assigned to the gabapentin group(if shivering occurs).

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is conducted in a double blinded manner; in this way, the person who performs the statistical analysis and records the necessary variables in each patient, the physician performing the procedure, and the patients themselves are unaware of the type of medication prescribed

Placebo
Not used

Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of AJA University of Medical Sciences

Street address

Etemadzadeh St. Fatemi St.

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2025-07-30, 1404/05/08

Ethics committee reference number

IR.AJAUMS.REC.1404.102

Health conditions studied

1

Description of health condition studied

Shivering after surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Shivering

Timepoint

Immediately after surgery until discharge from recovery

Method of measurement

According to the four criteria for grading postoperative tremor (table 1 mentioned in the proposal)

2

Description

Nausea and vomiting

Timepoint

Immediately after surgery until discharge from recovery

Method of measurement

By observing and assessing clinical symptoms and asking the patient questions

3

Description

Sedation

Timepoint

Immediately after surgery until discharge from recovery

Method of measurement

Any and all degrees of unresponsiveness to auditory and tactile stimuli According to the table grading of sedation(Table 2 mentioned in the proposal)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For group A, melatonin is administered as a single dose of 5 mg orally with 50 cc of water one hour before the operation. Then, after entering the operating room, for spinal anesthesia, they first receive 10 ml/kg of preloaded Ringer's serum fluid, which is kept at 22°C in the operating room, and then they are placed in a sitting position with a 25-gauge spinal needle and injected with 3 injections of 0.5% bupivacaine.

Category

Treatment - Drugs

2

Description

Intervention group: For group B, Gabapentin is administered as a single dose of 5 mg orally with 50 cc of water one hour before the operation. Then, after entering the operating room, for spinal anesthesia, they first receive 10 ml/kg of preloaded Ringer's serum fluid, which is kept at 22°C in the operating room, and then they are placed in a sitting position with a 25-gauge spinal needle and injected with 3 injections of 0.5% bupivacaine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

501AJA hospital

Full name of responsible person

Dr. Mohammadreza rafiei

Street address

Etemadzadeh St. , West Fatemi Ave.

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 6350 8609

Email

mo_rafiei@armyums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Army University of Medical Sciences

Full name of responsible person

Dr. Reza Mosaed

Street address

West fatemi, Etemadzadeh st.

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

Reza.mosaed@ajaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Army 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

Artesh University of Medical Sciences

Full name of responsible person

Mohammadreza Rafiei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Etemadzadeh street. West fatemi

City

Tehran

Province

Tehran
Postal code
1411718541
Phone
+98 21 8802 8933
Fax
+98 31 1263 1587
Email
mo_rafiei@armyums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mohamadreza Rafiei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Etemadzadeh street. West fatemi
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8802 8933
Fax
+98 31 1263 1587
Email
mo_rafiei@armyums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mohamadreza Rafiei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work

Anesthesiology
Street address
Etemadzadeh street. West fatemi
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8802 8933
Fax
+98 31 1263 1587
Email
mo_rafiei@armyums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All research data can be shared after unidentifying individuals

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

All researchers in the field of anesthesia and only by mentioning the source

Under which criteria data/document could be used

It can be used only for therapeutic and research purposes and by mentioning the source

From where data/document is obtainable

Dr. Mohammadreza Rafiei

What processes are involved for a request to access data/document

Send a request email to Dr. Rafiei and receive the data if the user approves

Comments