Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 block 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

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Iran (Islamic Republic of)

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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. scince the sampling is conveneince or available the first patient who visits is randomly assighed to the melatonin group(if shivering occurs) by receiving a white card and the next pateint who receives a black card is assighed to the gabapentin group(if shivering occurs).

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is conducted in adouble 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Army University of Medical Sciences
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
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
Mohamadreza Rafiei
Position
Associate professor
Latest degree
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Person responsible for updating data

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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 sata 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