# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison effects of intravenous ketamine with intrathecal meperidine in prevention of shivering in elective orthopedic surgery of lower extremity with spinal anesthesia

## Protocol summary

**Study aim**

Effect of meperedin intratecal in shivering after spinal anesthesia

**Design**

This study is a clinical trial with control group (phase 3), randomized (using computer random number list) and double-blind. The statistical population of this study is 150 patients who are candidates for spinal anesthesia in orthopedic lower limb surgeries in Imam Khomeini Hospital in Sari during the years 2017-2018.

**Settings and conduct**

The study was performed on patients who are candidates for spinal anesthesia in orthopedic lower limb surgery at Imam Khomeini Hospital in Sari. In the operating room, patients were given 5 ml per kg of normal saline at 37 ° C, 30 minutes before spinal anesthesia. Systolic and diastolic blood pressure and mean arterial pressure, heart rate and peripheral oxygen saturation and chills and body temperature were measured by sublingual thermometer 3 minutes before spinal anesthesia and then measured and recorded at 20 minute intervals.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: The patient's desire to participate in the study and gain informed consent؛ Age 18-65 years; Not fever. Exclusion criteria: Patients who received blood and blood products during surgery; Allergic reaction to meperidine or ketamine.

**Intervention groups**

Group K: Bupivacaine 0.5% 15 mg, which was increased to 4 ml with normal saline, was injected intrathecally, and immediately after spinal anesthesia, ketamine 0.5 mg / kg, which was reduced to 5 ml with normal saline. It was injected intravenously. Group M: bupivacaine 0.5% 15 mg and meperidine 0.2 mg / kg which was increased to 4 ml with normal saline and injected intrathecally and 5 ml normal saline was injected intravenously. Group C: Normal saline 5 ml intravenously and bupivacaine 0.5% 15 mg with normal saline volume 4 cc was injected intrathecally.

**Main outcome variables**

Shivering; Nausea and Vomiting؛ Heart rate drop.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160403027191N3**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **retrospective**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**

**Registration date**

2020-12-07, 1399/09/17

**Registrant information**

**Name**

Abdolmajid Gholinataj Jelodar

**Name of organization / entity**

Mazandaran University of Medical Science

**Country**

Iran (Islamic Republic of)

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+98 11 3304 4000

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-03-21, 1396/01/01

**Expected recruitment end date**

2019-01-21, 1397/11/01

**Actual recruitment start date**
2017-03-21, 1396/01/01
**Actual recruitment end date**
2019-01-21, 1397/11/01
**Trial completion date**
2019-01-21, 1397/11/01

**Scientific title**
Comparison effects of intravenous ketamine with intrathecal meperidine in prevention of shivering in elective orthopedic surgery of lower extremity with spinal anesthesia

**Public title**
Effect of Meperedin and Ketamin in prevention of shivering
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
The patient's desire to participate in the study and gain informed consent Elective lower extremity orthopedic surgery under spinal anesthesia Age>18and Age<65 ASA 1 and 2
**Exclusion criteria:**
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**
Target sample size: **150**
Actual sample size reached: **150**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
A total of 150 patients were randomly divided into three groups: intervention Ketamine (K), intervention Meperidine (M) and control group (C) using a list of computer random numbers. This was done by an anesthesia technician who was a fellow project.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The study was double-blind and the statistician, project physicians and patients were unaware of the patients' placement in the treatment groups and the data collection form was filled in by the project partner nurse who was unaware of the study groups. The lead researcher who injects the drug, as well as the medical staff responsible for caring for patients, are blinded.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Mazandaran University of Medical Sciences
**Street address**
Anesthesiology department ,Emam Khomeini Hospiral, Amir Mazandarani street
**City**
Sari
**Province**
Mazandaran
**Postal code**
48166-33131
**Approval date**
2016-04-29, 1395/02/10
**Ethics committee reference number**
Ir.mazums.rec.95.2400

## Health conditions studied

### 1

**Description of health condition studied**
Shivering
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
The amount of shivering
**Timepoint**
From three minutes after the onset of anesthesia to two hours later at twenty-minute intervals
**Method of measurement**
Shivering chart

## Secondary outcomes

### 1

**Description**
Body temperature
**Timepoint**
From three minutes after spinal anesthesia to two hours later at intervals of every twenty minutes
**Method of measurement**
Termometr

### 2

**Description**

Mean Arterial Pressure

**Timepoint**

From three minutes after spinal anesthesia to two hours later at intervals of every twenty minutes

**Method of measurement**

Saadat automatic pressure gauge

## Intervention groups

### 1

**Description**

Group K: Bupivacaine 0.5% 15 mg, which was increased to 4 ml with normal saline, was injected intrathecally, and immediately after spinal anesthesia, ketamine 0.5 mg / kg, which was reduced to 5 ml with normal saline. It was injected intravenously.

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: Group M: bupivacaine 0.5% 15 mg and meperidine 0.2 mg / kg which was increased to 4 ml with normal saline and injected intrathecally and 5 ml normal saline was injected intravenously.

**Category**

Treatment - Drugs

### 3

**Description**

Control group:Group C: Normal saline 5 ml intravenously and bupivacaine 0.5% 15 mg with normal saline volume 4 cc was injected intrathecally.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Emam Khomeini hospital

**Full name of responsible person**

Abdolmajid Gholinataj Jelodar

**Street address**

Department of Anesthesiology, Emam Khomeini hospital, Amir Mazandari street, Sari

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid saeedi

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Anesthesiology Department,Emam Khomeini Hospital,Amir Mazandarani street

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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**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Abdolmajid Gholi Nataj Jelodar

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Assistant professor
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**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
The study has already been done and the data is not available
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available