

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 meperidin 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)

Phone

+98 11 3304 4000

Email address

gholinataj54@mazums.ac.ir

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

lr.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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4815733971

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gholinataj54@mazums.ac.ir

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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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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Position
Assistant professor
Latest degree
Specialist
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Person responsible for updating data

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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