

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Prophylactic use of intravenous ondansetron versus ketamine - midazolam combination for prevention of shivering during spinal anesthesia

Protocol summary

Summary

The aim of this study was to compare the efficacy intravenous ondansetron with ketamine plus midazolam for prevention of shivering during spinal anesthesia. American Society of Anesthesiologists (ASA) I to II patients, aged 18-65 years, who were candidate for elective orthopedic surgery with spinal anesthesia were included in this study. The other inclusion criteria were patients who had no psychological disorder, cardiopulmonary disease, hypo- or hyperthyroidism, initial body temperature $> 38.0^{\circ}\text{C}$ or $< 36^{\circ}\text{C}$. Also, patients without known history of alcohol, substance abuse or history of receiving vasodilators or similar medications likely to alter thermoregulation were included into the present study. If there was any change in technique of anesthesia or severe bleeding which needed to blood transfusion, the patient was excluded from the study. Materials and Methods: Ninety patients, aged 18-65 years, undergoing lower extremity orthopedic surgery were included in the present study. Ninety spinal anesthesia was performed in all patients with hyperbaric bupivacaine 15 mg. The patients were randomly allocated to receive normal saline (Group C), ondansetron 8 mg IV (Group O) or ketamine 0.25mg/kg IV plus midazolam 37.5 $\mu\text{g/kg}$ IV (Group KM) immediately after spinal anesthesia. During surgery shivering scores were recorded at five minutes intervals. The operating room temperature was maintained at 24°C and it was standardized.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307155362N7**
Registration date: **2014-03-11, 1392/12/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences, Isfahan

Country

Iran (Islamic Republic of)

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+98 31 1273 2659

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Recruitment status

Recruitment complete

Funding source

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences

Expected recruitment start date

2009-03-20, 1387/12/30

Expected recruitment end date

2010-11-21, 1389/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic use of intravenous ondansetron versus ketamine - midazolam combination for prevention of shivering during spinal anesthesia

Public title

Prophylactic use of ondansetron versus ketamine - midazolam combination for prevention of shivering during spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias:(ASA) I to II patients; aged 18-65 years; candidate for elective orthopedic surgery with spinal anesthesia Exclusion criterias: psychological disorder; cardiopulmonary disease; hypo- or hyperthyroidism; initial body temperature > 38.0 °C or < 36 °C; without known history of alcohol or substance abuse ; history of receiving vasodilators or similar medications likely to alter thermoregulation; any change in technique of anesthesia ; sever bleeding which needed to blood transfusion

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences

Street address

Alzahra Hospital Sofe street Hakim Nezami junction

City

Isfahan

Postal code

8271618566

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

338

Health conditions studied**1****Description of health condition studied**

shivering after anesthesia

ICD-10 code

T88.5

ICD-10 code description

Hypothermia following anaesthesia

Primary outcomes**1****Description**

shivering

Timepoint

each 5 minutes untill 24 hours after surgery

Method of measurement

observation

Secondary outcomes**1****Description**

side effects of drugs such as
hullosination,nausea,vomitting and hypotension

Timepoint

after injection of drugs untill 24 hoiurs

Method of measurement

observation

Intervention groups**1****Description**

adding normal saline in control group

Category

Treatment - Drugs

2**Description**

adding 8 mg ondansetron intravenous in O group

Category

Treatment - Drugs

3**Description**

adding 0.25 mg ketamin and 37.5 mg midazolam
intravenous in KM group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Mohammadreza Safavi

Street address

Kashani hospital Kashani street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Safavi

Street address

Alzahra Hospital Sofe street Hakim Nezami junction

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Safavi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty