# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 ºC or < 36 ºC. 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 sever 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 µg/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)

**Phone**

+98 31 1273 2659

**Email address**

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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 ºC or < 36 ºC; 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**
**Street address**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences
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**Web page address**

## 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*