

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\mu\text{g}/\text{kg}$  IV (Group KM) immediately after spinal anesthesia. During surgery shivering scores were recorded at five minutes intervals. The operating room temperature was maintained at  $24^{\circ}\text{C}$  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

safavi@med.mui.ac.ir

##### 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 hoieurs

#### 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**

Alzahra Hospital Sofe street Hakim Nezami junction

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#### Person responsible for scientific inquiries

##### Contact

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**Position**

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#### Person responsible for updating data

##### Contact

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Anesthesiology and Critical Care Research Center,  
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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*