

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison between prophylactic low dose ketamine and ondansetron for prevention of shivering after spinal anesthesia for elective cesarean section

#### Protocol summary

##### Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is Comparison between prophylactic low dose ketamine and ondansetron for prevention of shivering after spinal anesthesia for elective cesarean section. Total of sample size is 117 patient with ages: 18-40 years old. Inclusion criteria are patients candidate for elective cesarean section with pfannenstiell incision, under spinal anesthesia. The patients with With a history of cardiovascular disease, allergy to ketamine or ondansetron will be excluded. Patients are randomly divided into three groups with table of random numbers by computer. Assessor of study and patients do not know about type of drug and grouping people. This study is 2-3 trial phase. First group receives 0.25 mg/kg of ketamin diluted in 10 ml normal saline, intravenously after spinal anesthesia. Second group receives 4 mg of ondansetron diluted in 10 ml of normal saline, intravenously after spinal anesthesia. Third group receives 10 ml of normal saline, intravenously after spinal anesthesia. Patients basic information such as age and sex, BMI, systolic and diastolic blood pressure, heart rate, intensity of patients shivering, dizziness, allergic reactions, nausea, vomiting and hallucinations during surgery and after surgery will be recorded in all three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040627258N1**

Registration date: **2016-05-14, 1395/02/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-14, 1395/02/25

##### Registrant information

###### Name

Nazli Arbabi

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3222 2922

###### Email address

arbabi.n@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2015-12-06, 1394/09/15

##### Expected recruitment end date

2016-06-04, 1395/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison between prophylactic low dose ketamine and ondansetron for prevention of shivering after spinal anesthesia for elective cesarean section

##### Public title

The effect of ketamine and ondansetron for prevention of shivering after surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: patients candidate for elective cesarean section with pfannenstiell incision under spinal anesthesia; ASA (American society of anesthesiology) physical class one and two; Patient with ages: 18-40 years old. Exclusion Criteria: history of kidney problems; cardiovascular disease; liver disease; mental illness; seizures; glaucoma; receiving blood products during surgery; lack of patient satisfaction; allergy to ketamine and ondansetron.

## Age

From **18 years** old to **40 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **117**

## 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

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

##### Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

##### City

Ahvaz

##### Postal code

#### Approval date

2015-12-05, 1394/09/14

#### Ethics committee reference number

IR.AJUMS.REC.1394.498

## Health conditions studied

### 1

#### Description of health condition studied

shivering during and after spinal anesthesia

#### ICD-10 code

R68.0

#### ICD-10 code description

Hypothermia, not associated with low environmental temperature

## Primary outcomes

### 1

#### Description

Intensity of shivering patients

#### Timepoint

Every 10 minute to 1 hour after surgery

#### Method of measurement

Based on the score shivering (0-4)

### 2

#### Description

Systolic blood pressure and diastolic blood pressure

#### Timepoint

Before administration and every ten minutes to an hour after surgery

#### Method of measurement

By using the pressure gauge - in millimeters of mercury

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: Prescription 0.25 mg/kg of ketamin diluted in 10 ml normal saline, intravenously after spinal anesthesia.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Prescription 4 mg of ondansetron diluted in 10 ml of normal saline, intravenously after spinal anesthesia.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: Prescription 10 ml of normal saline, intravenously after spinal anesthesia.

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Khomeini Hospital

**Full name of responsible person**

Mohammad Reza Gusheh

**Street address**

Khomeini Hospital, Shahid Ahvazian St., Ahvaz

**City**

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**Other areas of specialty/work****Street address**

Ahvaz Jundishapur University of Medical Sciences,  
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**City**

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**Fax****Email**

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**Web page address**

-

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor For Research Of Ahvaz Jundishapur  
University of Medical Sciences

**Full name of responsible person**

Nader Saki

**Street address**

Vice chancellor For Research Of Ahvaz Jondishapour  
University of Medical Sciences, Ground Floor, Central  
Library, Ahvaz Jundishapur University of Medical  
Sciences, GolestanBLvd., Ahvaz

**City**

Ahvaz

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice chancellor For Research Of Ahvaz Jundishapur  
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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Nazli Arbabi

**Position**

Resident of anesthesiology

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Ahmad Reza Mohtadi

**Position**

anesthesiologist

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## Person responsible for updating data

**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Sanaz Nazari

**Position**

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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*