

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of prophylactic effect of ondansetron and ketamine on spinal anesthesia-induced hypotension in cesarean section

#### Protocol summary

##### Summary

Objectives: Among regional anesthesia techniques, spinal anesthesia is more practical due to ease of technique, more speed, reliable nerve block, using minimum dose of local anesthetics, and the cost-effectiveness. However, this method is also associated with complications, and hypotension induced by sympathetic block is the most common of them. Ondansetron, as a serotonin receptor antagonist can reduce hypotension-induced by spinal anesthesia. Next drug is ketamine which is used for analgesia during labor. Ketamine is a N-methyl-D-aspartate (NMDA) receptor antagonist and a common drug used to induce anesthesia in pregnant women. The aim of this study is to compare prophylactic effect of ondansetron and ketamine on spinal anesthesia induced hypotension in cesarean section. Design: Block randomization, triple blind, with placebo, trial phase 2, including 93 patients under elective cesarean section. Setting and conduct: Lidocaine 5%, 75 milligrams, injection into the subdural space to induce spinal anesthesia. Participants including major eligibility criteria: All women who are supposed to undergo elective cesarean section. Intervention: Ondansetron, 4 milligrams (2 ml), slow IV injection in 30 seconds. Ketamine, 25 milligrams (volume 2 ml with distilled water), IV injection. Normal saline, 2 ml, IV injection in control group. Main outcome measures: Systolic blood pressure, diastolic blood pressure, arterial O2 saturation, heart rate, Level of consciousness.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013102315137N1**

Registration date: **2014-01-28, 1392/11/08**

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

Last update:

Update count: **0**

##### Registration date

2014-01-28, 1392/11/08

##### Registrant information

###### Name

Saeid Bagherbandi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3505

###### Email address

dr.bagherbandi@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Arak University of Medical Sciences

##### Expected recruitment start date

2013-07-23, 1392/05/01

##### Expected recruitment end date

2014-03-21, 1393/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of prophylactic effect of ondansetron and ketamine on spinal anesthesia-induced hypotension in cesarean section

##### Public title

Comparison of the effects of ondansetron and ketamine on spinal anesthesia-induced hypotension in women

undergoing cesarean section

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: Pregnant women candidate for elective cesarean with spinal anesthesia who referred to Taleghani hospital, Arak. Exclusion criteria: Dissatisfaction of patient; Hypertension; Cardiovascular diseases; Body mass index upper 35; History of liver disease; History of migraine and seizure; Allergy to ondansetron; History of taking any medications that affect blood pressure or heart rate; Failure of spinal anesthesia; In top spinal cord Injuries; Need to additional drugs

### **Age**

From **15 years** old to **45 years** old

### **Gender**

Female

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **93**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

Injecting person, and the person responsible for collecting data are not aware of injecting drug. Syringes containing drug are prepared by someone else and are only labeled by the letters A, B, and C.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

##### **Street address**

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

##### **City**

Arak

##### **Postal code**

#### **Approval date**

2013-07-15, 1392/04/24

#### **Ethics committee reference number**

14-149-92

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Hypotension

#### **ICD-10 code**

I95, I95.0

#### **ICD-10 code description**

Hypotension due to drugs

## **Primary outcomes**

### 1

#### **Description**

Systolic blood pressure

#### **Timepoint**

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

#### **Method of measurement**

Sphygmomanometer

### 2

#### **Description**

Diastolic blood pressure

#### **Timepoint**

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

#### **Method of measurement**

Sphygmomanometer

### 3

#### **Description**

Arterial O2 saturation

#### **Timepoint**

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

#### **Method of measurement**

Pulse oximeter

### 4

#### **Description**

Heart rate

#### **Timepoint**

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

#### **Method of measurement**

Cardiac monitor

### 5

#### **Description**

Level of consciousness

#### **Timepoint**

Before spinal anesthesia and thirty minutes after taking drug

#### **Method of measurement**

Ramsay score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention 1. Ondansetron, 4 milligrams (2 ml), slow IV injection in 30 seconds; made in Tehran Chemistry Pharma Co. with chemical composition (RS)-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-2,3-dihydro-1H-carbazol-4(9H)-one

#### Category

Prevention

### 2

#### Description

Intervention 2. Ketamine, 25 milligrams (volume 2 ml with distilled water), IV injection; made in TRITTAU company, GERMANY, with chemical composition (RS)-2-(2-Chlorophenyl)-2-(methylamino)cyclohexanone

#### Category

Prevention

### 3

#### Description

Intervention 3. Normal saline, 2 ml, IV injection in control group.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani hospital

##### Full name of responsible person

Dr Saeid Bagherbandi

##### Street address

Taleghani hospital. Imam Khomeini street. Arak. Iran

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences, Vice Chancellor for Research

##### Full name of responsible person

Dr Saeed Changizi Ashtiani

##### Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

#### City

Arak

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak University of Medical Sciences, Vice Chancellor for Research

#### 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

Arak University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bagherbandi

##### Position

Anesthesiology Assistant

##### Other areas of specialty/work

##### Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

##### City

Arak

##### Postal code

##### Phone

+98 86 3417 3505

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##### Email

dr.bagherbandi@arakmu.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bagherbandi

##### Position

General practitioner

##### Other areas of specialty/work

##### Street address

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bagherbandi

**Position**

Anesthesiology resident

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

Arak University of Medical Sciences. Basij Square.

Sardasht. Arak. Iran

**City**

Arak

**Postal code****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*