

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of intravenous ondansetron on hypotension during cesarean section

#### Protocol summary

##### Summary

After approval of research board of Emam Khomeini hospital and ethics committee of Urmia University Of Medical Sciences, with the aim of evaluation of intravenous ondansetron effect on hypotension during cesarean section, a randomized double-blind clinical trial will be conducted. After obtaining informed written consent 70 parturients aged at 20-40 years old with American Society of Anesthesiologists (ASA) class I-II scheduled for the elective cesarean section with spinal anesthesia will be asked to participate in the study. The patients with the history of hypertension, antihypertension drugs consumption, gastrointestinal diseases, motion sickness, allergy to ondansetron, glaucoma, preeclampsia, eclampsia, psychotic disorders and antiemetic drugs use during last 24 hours will be excluded from the study. Using random allocation software, the patients will be divided into study (O) and control (S) groups with equal numbers. In operation room, standard monitoring including noninvasive blood pressure, pulse oximetry and EKG will be attached. 5 minutes before spinal anesthesia, study and control group patients will receive 6 milligram intravenous ondansetron and normal saline solution with equal volumes respectively. The patients will receive 5 ml/Kg Ringer solution intravenously and then spinal anesthesia using 12.5 mg hyperbaric bupivacaine will be induced at sitting position and at L3-L4 intervertebral level. After injecting the local anesthetic in subarachnoid space, the patient will be turned back to supine position and the operating table will be tilted 10-15 degrees to prevent aortocaval compression induced hypotension. Oxygen will be administered to the patients during surgery using face- mask. Blood pressures will be measured and recorded at minutes, 0,3,6,9,10,15,20,25,30 and 5-10 milligram intravenous ephedrine will be administered if systolic pressure decreases more than 25 percent of basic systolic or under 100 mm Hg. Mean values of blood pressure, heart rate and also nausea, vomiting and

shivering during surgery and stay at recovery unit will be recorded and analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017033025600N3**

Registration date: **2017-04-15, 1396/01/26**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-04-15, 1396/01/26

##### Registrant information

##### Name

Shahram Shokohi

##### Name of organization / entity

Urmia University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 8967

##### Email address

shokohi.sh@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor of research, Urmia University Of Medical Sciences

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of intravenous ondansetron on hypotension during cesarean section

**Public title**

Effect of intravenous ondansetron on arterial blood pressure

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Parturients aged at 20-40 years old with American Society of Anesthesiologists (ASA) class I-II scheduled for the elective cesarean section with spinal anesthesia Exclusion criteria: History of hypertension; antihypertension drugs consumption; gastrointestinal diseases; motion sickness; allergy to ondansetron; glaucoma; preeclampsia; eclampsia; psychotic disorders and antiemetic drugs use during last 24 hours

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**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**

Urmia University Of Medical Sciences

**Street address**

Urgence street, Resaalat boulevard,

**City**

Urmia

**Postal code**

5714783734

**Approval date**

2016-10-26, 1395/08/05

**Ethics committee reference number**

IR.umsu.rec.1395.301

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

Spinal anesthesia induced hypotension during cesarean section

**ICD-10 code**

O74.6

**ICD-10 code description**

Other complications of spinal and epidural anaesthesia during labour and delivery

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

Hypotension during cesarean section

**Timepoint**

at minutes 0,3,6,10,15,20,25,30

**Method of measurement**

None invasive blood pressure measuring

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

Nausea during surgery and stay in recovery unit

**Timepoint**

At any time during surgery and stay in recovery unit

**Method of measurement**

By asking the patient

**2****Description**

Vomiting during surgery and stay in recovery unit

**Timepoint**

At any time during surgery and stay in recovery unit

**Method of measurement**

By asking the patient

**3****Description**

Shivering during surgery and stay in recovery unit

**Timepoint**

At any time during surgery and stay in recovery unit

**Method of measurement**

By asking the patient

**Intervention groups**

## 1

### Description

Intravenous administration of 6 milligram ondansetron 5 minutes before spinal anesthesia

### Category

Treatment - Drugs

## 2

### Description

Intravenous administration of 5 milliliters of normal saline solution 5 minutes before spinal anesthesia

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Motahari teaching hospital of Urmia

#### Full name of responsible person

Dr. Shahram Shokohi

#### Street address

Kashani avenue

#### City

Urmia

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice chancellor of resresearch, Urmia University Of Medical Sciences

#### Full name of responsible person

Dr. Iraj Mohebbi

#### Street address

Urgence avenue, Jahad street, Resalat boulevard

#### City

Urmia

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor of resresearch, Urmia 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

Urmia University Of Medical Sciences

#### Full name of responsible person

Dr. Shahram Shokohi

#### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

Department of anesthesiology, Emam Khomeini teaching hospital, Ershad avenue, Modarres boulevard

#### City

Urma

#### Postal code

5715781351

#### Phone

+98 44 3346 8967

#### Fax

+98 44 3346 8967

#### Email

shokohi.sh@umsu.ac.ir, shokohi725@yahoo.com, dr.s.shokohi@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Urmia University Of Medical Sciences

#### Full name of responsible person

Dr. Shahram Shokohi

#### Position

Assistant Professor

#### Other areas of specialty/work

#### Street address

Department of anesthesiology, Emam Khomeini teaching hospital, Ershad avenue, Modarres boulevard,

#### City

Urmia

#### Postal code

571578135

#### Phone

+98 44 3346 8967

#### Fax

00894433468967

#### Email

shokohi.sh@umsu.ac.ir; shokohi725@yahoo.com; dr.s.shokohi@gmail.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Urmia University Of Medical Sciences

**Full name of responsible person**

Dr. Shahram Shokohi

**Position**

Assistant professor

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

Department of anesthesiology, Emam Khomeini  
teaching hospital, Ershahd street, Modarres boulevard

**City**

Urmia

**Postal code**

571578135

**Phone**

+98 44 3346 8967

**Fax**

+98 44 3346 8967

**Email**

shokohi.sh@umsu.ac.ir

**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*