# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effectiveness of ondansetron on hemodynamic changes following spinal anesthesia in pregnant women and comparison with prehydration and prophylactic ephedrine

## Protocol summary


**Summary**

Purpose of the study: the effectiveness of ondansetron on hemodynamic changes following spinal anesthesia in pregnant women and its comparison with prehydration and prophylactic ephedrine. Design: single-blind, randomized, blocking study. Samples were divided into four groups using randomized block design. Study population: pregnant women aged between 18 and 40 years undergoing cesarean section. Inclusion criteria: ASA I and ASA II diseases; aged between 18 and 40 years; single or twin gestations; undergoing Cesarean section or spinal anaesthesia for emergency Caesarean; not using anti-migraine therapeutics, SSRI or MAO inhibitors; not being allergic to ondansetron; absence of psychological disorders; and not consuming drugs or alcohol. Exclusion criteria: Failure of spinal anesthesia; untreatable pain with 50 micrograms of fentanyl after the onset of surgery; bleeding more than expected (500 cc in single gestation and 1000 cc in twin gestations); numbness extending beyond the dermatome T4 level according to skin testing with needle point; need to expand incision during surgery due to the surgical complications; and having major complications during surgery. Sample: 120. Study Intervention: ondansetron, ephedrine and ringer. Time of intervention: during anesthesia for cesarean The outcome of the study: Clinical information of patients will be recorded when they enter the operating room. Maternal blood pressure, ECG and heart rate are recorded before and after the anesthesia.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015102813159N7**
Registration date: **2016-01-21, 1394/11/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-01-21, 1394/11/01

**Registrant information**


**Name**
Shima Sheybani
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 51 3764 7230
**Email address**
sheybanish@mums.ac.ir


**Recruitment status**

**Recruitment complete**


**Funding source**

Vice Chancellor for Research of Mashhad University of Medical Sciences


**Expected recruitment start date**

2015-12-22, 1394/10/01

**Expected recruitment end date**

2016-12-21, 1395/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of ondansetron on hemodynamic changes following spinal anesthesia in pregnant women and comparison with prehydration and prophylactic

ephedrine

**Public title**
The effectiveness of ondansetron on pregnant women
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: ASA I and ASA II diseases; aged between 18 and 40 years; single or twin gestations; undergoing Cesarean section or spinal anaesthesia for emergency Caesarean; not using anti-migraine therapeutics, SSRI or MAO inhibitors; not being allergic to ondansetron; absence of psychological disorders; and not consuming drugs or alcohol. Exclusion criteria: Failure of spinal anesthesia; untreatable pain with 50 micrograms of fentanyl after the onset of surgery; bleeding more than expected (500 cc in single gestation and 1000 cc in twin gestations); numbness extending beyond the dermatome T4 level according to skin testing with needle point; need to expand incision during surgery due to the surgical complications; and having major complications during surgery.
**Age**
From **18 years** old to **40 years** old
**Gender**
Female

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **120**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Mashhad University of Medical Sciences
**Street address**
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad
**City**
Mashhad
**Postal code**
**Approval date**
2015-07-22, 1394/04/31
**Ethics committee reference number**
IR.mums.FM.REC.1394.208

## Health conditions studied

### 1

**Description of health condition studied**
pregnant women
**ICD-10 code**
O82.8
**ICD-10 code description**
Other single delivery by caesarean section

## Primary outcomes

### 1

**Description**
Maternal blood pressure
**Timepoint**
Before and after anesthesia
**Method of measurement**
Clinical mercury Manometer; mmHg

## Secondary outcomes

### 1

**Description**
Maternal heart rate
**Timepoint**
Before and after anesthesia
**Method of measurement**
Monitoring Compact; in minuets

## Intervention groups

### 1

**Description**
Control group: 4 mg of placebo drugs 5 minutes before spinal anesthesia
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 1: 4 mg of Ondansetron 5 minutes before spinal anesthesia.
**Category**
Treatment - Drugs

### 3

**Description**
Intervention group 2: 25 mg of Ephedrine injection to the

muscle 25 minutes before spinal anesthesia

**Category**

Treatment - Drugs

**4**

**Description**

Intervention group 3: 500 ml of Ringer 20 minutes before spinal anesthesia

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Shima Sheybani

**Street address**

Ghaem Hospital, Ahmadabad Avenue

**City**

Mashhad

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad

**City**

Mashhad

**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, Mashhad 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**

Ghaem Hospital

**Full name of responsible person**

Mohsen Saber Ranjbar

**Position**

Assistant Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

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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*