

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Evaluation of Prophylactic ondansetron in prevention of maternal hypotension following spinal anesthesia in women undergoing cesarean section

#### Protocol summary

##### Study aim

Study of the efficacy of intravenous ondansetron in prevention of hypotension following spinal anesthesia in women undergoing cesarean section

##### Design

This is a controlled double-blinded clinical trial study will be conducted on 60 women undergoing cesarean section with spinal anesthesia. After coordination and obtaining informed consent, the patients (n=30per group) will be randomly assigned into two groups of intravenous ondansetron (10 mg) or normal saline at the same dose and will be received the medications before spinal anesthesia.

##### Settings and conduct

From pregnant women candidate for cesarean section with spinal anesthesia referring to Imam Khomeini hospital, Ahvaz, total of 30 patients will be selected and randomly divided into 2 groups. In the first group, ondansetron 10 mg will be injected intravenously before spinal anesthesia. In the second group, normal saline 10 mg will be used. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

##### Participants/Inclusion and exclusion criteria

- Inclusion criteria: age between 18 to 40 years, Candidate for elective cesarean section, no contraindication for spinal anesthesia, Consent to participate in the study; Exclusion criteria: Hypertension, weight more than 100 kg, motion sickness, cardiovascular disease, liver disease, migraine, allergy to ondansetron medications group, using any medication which effect the blood pressure or heart rate.

##### Intervention groups

In the first group, ondansetron 10 mg will be injected intravenously before spinal anesthesia. In the second group, normal saline 10 mg will be used as control.

##### Main outcome variables

All patients will be examined for Hemodynamics change (HR, SBP, DBP) and side-effects after surgery (nausea, vomiting, chills, itching) up to 2 hours after the patient entry to recovery.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191015045121N1**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **prospective**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

##### Registration date

2019-10-26, 1398/08/04

##### Registrant information

##### Name

Maryam Mofrad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3001 3374

##### Email address

mofrad.m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-01, 1398/09/10

##### Expected recruitment end date

2020-03-10, 1398/12/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of Prophylactic ondansetron in prevention of maternal hypotension following spinal anesthesia in women undergoing cesarean section

**Public title**

Effect of ondansetron in prevention of hypotension following spinal anesthesia in cesarean section

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 18 to 40 years Candidate for elective cesarean section no contraindication for spinal anesthesia

**Exclusion criteria:**

Patients with hypertension Weight more than 100 kg Motion sickness Cardiovascular disease Liver disease Migraine Allergy to ondansetron medications group Using any medication which effect the blood pressure or heart rate

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly assigned into two groups of experimental and control. Each patient is given a number from 1 to 60 and assignment of patients into the study groups will be done by table of random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Intervention (receiving normal saline orondansetron) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Also patients and statistical analyzer will not know about patient grouping.

**Placebo**

Not 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**

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733118

**Approval date**

2019-08-19, 1398/05/28

**Ethics committee reference number**

IR.AJUMS.REC.1398.415

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

Hypotension after cesarean section

**ICD-10 code**

I95.81

**ICD-10 code description**

Postprocedural hypotension

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

Systolic and diastolic blood pressure

**Timepoint**

At the beginning of the study (before the intervention) and then every 5 minutes

**Method of measurement**

Mercury barometer

**2****Description**

side-effects after surgery

**Timepoint**

up to 2 hours after the patient entry to recovery.

**Method of measurement**

presence of Itching, chills, nausea and vomiting based on direct observation

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: ondansetron 10 mg (Demitron, Tehran Shimi CO., Iran) will be injected intravenously 5 min before performing spinal anesthesia.

#### Category

Prevention

### 2

#### Description

Control group: normal saline 10 mg will be injected intravenously 5 min before performing spinal anesthesia

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Maryam Mofrad

##### Street address

Imam Khomeini Hospital, Azadegan St.

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6193673111

##### Phone

+98 21 3222 2818

##### Email

Dr.mofrad.m@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Badavi

##### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Blvd.

##### City

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##### Province

Khuzestan

##### Postal code

6135733118

##### Phone

+98 61 3373 8383

##### Email

badavim@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Ahmad Reza Mohtadi

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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mohtadi-ar@ajums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Ahmad Reza Mohtadi

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for updating data

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**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ahmad Reza Mohtadi

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available