

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

#### Protocol summary

##### Study aim

Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

##### Design

The clinical trial has a control group, with parallel groups, double-blind, approved, phase 2-3 in 180 patients. Randomization is by using <https://www.sealedenvelope.com> website.

##### Settings and conduct

Intervention group one: patients will receive Ephedrine 10 mg , during 5 minutes before spinal anesthesia . Intervention group two: patients will receive Ondansetron 8 mg , during 5 minutes before spinal anesthesia. Control group: patients will receive 10 cc normal saline as placebo during 5 minutes before spinal anesthesia. Anesthesiologist and surgeon were blinded, Neither the participants nor the investigators involved in data collection and assessing the outcomes are aware of the identity of the target drugs.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18 years, Elective cesarean section, ASA classification I-II, Term and singleton pregnancy. Exclusion Criteria: Diabetes, Hypertension , Body mass index 40, Complicated pregnancy such as placenta Previa, preeclampsia, history of Long QT syndrome, history of Electrolyte imbalance, Contraindication to the spinal anesthesia, Failed spinal block or total spinal converted to general anesthesia, history of allergy to or side effects to the study drugs.

##### Intervention groups

Intervention group one: patients will receive Ephedrine 10 mg , during 5 minutes before spinal anesthesia . Intervention group two: patients will receive Ondansetron 8 mg , during 5 minutes before spinal anesthesia. Control group: patients will receive 10 cc normal saline as placebo during 5 minutes before spinal anesthesia.

##### Main outcome variables

Hemodynamic changes ,nausea and vomiting, motor block duration .

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N106**

Registration date: **2021-01-26, 1399/11/07**

Registration timing: **prospective**

Last update: **2021-01-26, 1399/11/07**

Update count: **0**

##### Registration date

2021-01-26, 1399/11/07

##### Registrant information

##### Name

Farzaneh Masihi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4270

##### Email address

masihif@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-02, 1399/11/14

##### Expected recruitment end date

2021-04-21, 1400/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

**Public title**

Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

**Purpose**

Prevention

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

Age 18 years Elective cesarean section ASA classification I-II Term and singleton pregnancy

**Exclusion criteria:**

DM Hypertensive disorder Body Mass Index 40 Complicated pregnancy such as placenta Previa, preeclampsia History of Long QT syndrome History of Electrolyte imbalance Contraindication to spinal anesthesia Failed spinal block or total spinal converted to general anesthesia History of allergy to or side effects to the study drugs.

**Age**

From **18 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly divided into three groups of drugs and placebo. Randomization is by using <https://www.sealedenvelope.com> website.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Medications were prepared by an anesthesia nurse who were totally unaware of the nature of the study who is verified the allocation and prepared ondansetron 8 mg with 0.9% saline solution to a total volume of 10 mL or a placebo of 0.9% saline solution 10 mL and ephedrine 10 mg with 0.9% saline solution to a total volume of 10 mL. While anesthesiologist and surgeon were blinded, Neither the participants nor the investigators involved in data collection and assessing the outcomes are aware of the identity of the target drugs. The syringes had no identifying markers indicating group allocation. The nurse injected the contents of the 10-mL syringe

intravenously over 60 s, 5 min before the lumbar puncture. The anesthetist is blinded to group allocation.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Approval date**

2020-12-15, 1399/09/25

**Ethics committee reference number**

IR .SUMS.MED.REC.1399.471

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

cesarean

**ICD-10 code**

O82

**ICD-10 code description**

Encounter for cesarean delivery without indication

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

Hemodynamic data (SBP, DBP, MAP, HR, and SaO2)

**Timepoint**

During Operation

**Method of measurement**

Monitoring

**Secondary outcomes**

## 1

### Description

Duration of motor block

### Timepoint

7 and 15 min after intrathecal injection

### Method of measurement

Bromage scale

## Intervention groups

### 1

#### Description

Intervention group one: patients will receive Ephedrine (Aterop, Belgium) 10 mg , during 5 minutes before spinal anesthesia .

#### Category

Prevention

### 2

#### Description

Intervention group two: patients will receive Ondansetron (Exir, Iran) 8 mg , during 5 minutes before spinal anesthesia.

#### Category

Prevention

### 3

#### Description

Control group: patients will receive 10 cc normal saline as placebo during 5 minutes before spinal anesthesia.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hafez Hospital

##### Full name of responsible person

Parnian Baghban

##### Street address

Hafez Educational and Medical Center, Abivardi,  
Chamran St.

##### City

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347871946

##### Phone

+98 71 3647 9531

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Hafez@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaianzadeh

##### Street address

Vice chancellor of research, 7th floor of central  
building of Shiraz University of Medical Sciences,  
Zand street

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+98 71 3647 4270

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masihifarzaneh@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Parnian Baghban

##### Position

Anesthesiology Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand  
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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Saied Khademi  
**Position**  
Cardio-anesthesiologist  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for updating data

### Contact

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BS in anesthesia/English Consultant  
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Master  
**Other areas of specialty/work**  
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7134844119  
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**Email**  
masihifarzaneh@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Its against our policy.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available