

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

#### Protocol summary

##### Study aim

determination and comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

##### Design

Randomised, controlled , parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an excel

##### Settings and conduct

This study is a randomized double-blind clinical trial that randomization will be done by usind random numbers. this study will be done in Beheshti Hospital.

##### Participants/Inclusion and exclusion criteria

Age between 18 to 45 years old ASA number 1 and 2 Patient is cesarian candida that term pregnancy Patient has no disease like hypertention Patient has no uncontrolled diabet Patient has no allergy to ondansetron or local anesthtic drug no forbid for spinal anesthesia Patient dosent use drugs which effect on HT35 receptor

##### Intervention groups

Patients will be randomly divided into three groups consist of receiving 6 mg of ondansetron, 8 mg of ondansetron, and distilled water. They are injected intravenously and then the patients are subjected to spinal anesthesia. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and arterial blood oxygen saturation are measured and recorded every 15 minutes during surgery and every 15 minutes during the recovery period by an observer who is not by the research team. Any complication is recorded if it occurs during appropriate treatment

##### Main outcome variables

Systolic blood pressure, diastolic blood pressure, heart rate, mean arterial pressure, arterial oxygen saturation, nausea, vomiting, duration of surgery,duration of stay in

recovery,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191109045371N1**

Registration date: **2020-10-14, 1399/07/23**

Registration timing: **retrospective**

Last update: **2020-10-14, 1399/07/23**

Update count: **0**

##### Registration date

2020-10-14, 1399/07/23

##### Registrant information

##### Name

Farhad Hasanvand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3625 6966

##### Email address

farhadhasanvand94@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### Expected recruitment end date

2020-07-21, 1399/04/31

##### Actual recruitment start date

2020-03-20, 1399/01/01

##### Actual recruitment end date

2020-07-21, 1399/04/31

**Trial completion date**

2020-08-22, 1399/06/01

**Scientific title**

comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

**Public title**

comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

**Purpose**

Treatment

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

Age between 18 to 45 years old ASA number 1 and 2  
Patient is cesarian candida that term pregnancy Patient has no disease like hypertention Patient has no uncontrolled diabet Patient has no allergy to ondansetron or local anesthtic drug no forbid for spinal anesthesia  
Patient dosent use drugs which effect on HT35 receptor

**Exclusion criteria:****Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

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

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study ,patients were divided on a basis of Random block making, into blocks consisting of six peoples.in each block, two patients received 8 milligrams of ondansetron, two patients received 6 milligrams of ondansetron, and two patients received normal saline. then by use of Random digits table, 15 different blocks of the so called blocks were randomly chosen. Drugs were drawn in three syringes of the same size and color by an out-of-study anesthesiologist and for every patient proportionate to his group, were given to the main anesthesiologist. Patient, main anesthesiologist, the person in charge of collecting and recording datas were unaware of the Type of the drug that was used.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Drugs were drawn in three syringes of the same size and color by an out-of-study anesthesiologist and for every

patient proportionate to his group, were given to the main anesthesiologist. Patient, main anesthesiologist, the person in charge of collecting and recording datas were unaware of the Type of the drug that was used.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Isfahan University of Medical Sciences

**Street address**

No 48,bijan alley , hakim nezami Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8175976665

**Approval date**

2019-06-02, 1398/03/12

**Ethics committee reference number**

IR.MUI.MED.REC.1398.446

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

cesarean section

**ICD-10 code**

O75.82

**ICD-10 code description**

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

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

Blood pressure

**Timepoint**

Befor operation and every 15 minute during operation and recovery

**Method of measurement**

mercury barometer

## 2

### **Description**

blood oxygen saturation

### **Timepoint**

Befor operation and every 15 minute during operation and recovery

### **Method of measurement**

puls oxymeter

## 3

### **Description**

heart rate

### **Timepoint**

Befor operation and every 15 minute during operation and recovery

### **Method of measurement**

puls oxymeter

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: patients take 6 mg ondansetron

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: patients take 8 mg ondansetron

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Control group: patients take 4cc distilled water

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Beheshti hospital

##### **Full name of responsible person**

Farhad Hasanvand

##### **Street address**

Felezi bridge, Motahari ave

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BEHESHTI@mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

shaghayegh haghju

##### **Street address**

Hezar zhrub ave

##### **City**

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8174673461

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#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Hamid Reza Shetabi

##### **Position**

Professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

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Esfahan University of Medical Sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Other areas of specialty/work**  
General Practitioner  
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farhadhasanvand94@gmail.com

## 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