# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables and the need for ephedrine in women candidates for cesarean section under spinal anesthesia

## Protocol summary

**Study aim**
Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables in women candidates for cesarean section under spinal anesthesia

**Design**
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 is performed on 60 patients. Random allocation software version 1.0 is used for randomization under Windows.

**Settings and conduct**
This study is performed on women candidates for cesarean section under spinal anesthesia in Kosar operating room of Shahid Sadoughi Hospital in Yazd. Prior to spinal anesthesia, the study drug or placebo is injected intravenously and then hemodynamic variables are measured and recorded during surgery and during recovery. This study is double-blind and neither the researcher nor the patient knows the type of drug prescribed, so that the drugs are prepared and coded in three identical syringes and the third person injects the drug for the patient based on the specified code.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Pregnant women aged 20-35 years, Class I ASA, non-emergency cesarean section, spinal anesthesia Non-inclusion criteria: dissatisfaction with the study, diabetes, preeclampsia and eclampsia, severe heart, lung, kidney and liver disease, drug addiction

**Intervention groups**
Intervention group1: In this group, granisetron at a dose of 3 mg equivalent to 3 ml is injected slow intravenously immediately before spinal anesthesia. Intervention group 2 : In this group, ondansetron in a dose of 4 mg in a volume of 3 ml is injected slowly into intravenous patients immediately before spinal anesthesia. Control group: In this group, 3 ml normal saline is injected slow intravenously immediately before spinal anesthesia.

**Main outcome variables**
Systolic blood pressure; diastolic blood pressure; mean arterial blood pressure; heart rate

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20100102002963N35**
Registration date: **2022-03-19, 1400/12/28**
Registration timing: **prospective**

Last update: **2022-03-19, 1400/12/28**
Update count: **0**

**Registration date**
2022-03-19, 1400/12/28

**Registrant information**
**Name**
Shekoufeh Behdad
**Name of organization / entity**
Shahid Sadoughi University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2022-05-05, 1401/02/15
**Expected recruitment end date**
2022-08-06, 1401/05/15
**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables and the need for ephedrine in women candidates for cesarean section under spinal anesthesia

**Public title**

Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables and the need for ephedrine in women candidates for cesarean section under spinal anesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

20-35 years old women with term pregnancy American Society of Anesthesia (ASA) physical status I Non-emergency cesarean delivery Spinal anesthesia

**Exclusion criteria:**

dissatisfaction with the study diabetes preeclampsia and eclampsia severe heart, lung, kidney and liver disease drug addiction

**Age**

From **20 years** old to **35 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomly allocate 60 eligible applicants, we randomly divide them into three groups of 20 people. For this purpose, we use Random allocation software version 1.0 under Windows to create a sequence, and by using this software we make A list which is specified from 1 to 60 with group A or B or C treatment By Using this list, we give the first person who is eligible to enter the study, number one and the last person the number 60, then based on the random allocation list and by the software, it is determined which group A or B or C each person is in. Each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug is given to patients by a third person who is not involved in evaluating patients and recording results.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and researchers themselves are unaware of which medication the patient has received, in this way, each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug is given to patients by a third person who is not involved in evaluating patients and recording results.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Medical School - Shahid Sadoughi University of Medical Sciences, Yazd

**Street address**

Faculty of Medicine. Shohadayegomnam Blv.Yazd

**City**

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**Province**

Yazd

**Postal code**

8915887857

**Approval date**

2021-11-18, 1400/08/27

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1400.474

## Health conditions studied

### 1

**Description of health condition studied**

Hemodynamic variables and hypotension after spinal anesthesia in the women undergoing cesarean section

**ICD-10 code**

I95.81

**ICD-10 code description**

Postprocedural hypotension

## Primary outcomes

### 1

**Description**

Systolic blood pressure

**Timepoint**

Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes

**Method of measurement**

Using monitoring device

### 2

**Description**
Diastolic Blood Pressure
**Timepoint**
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
**Method of measurement**
Using monitoring device

### 3

**Description**
Mean Arterial Pressure
**Timepoint**
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
**Method of measurement**
Using monitoring device

### 4

**Description**
Heart Rate
**Timepoint**
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
**Method of measurement**
Using monitoring device

### 5

**Description**
Drop in systolic blood pressure below 90 mm Hg
**Timepoint**
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
**Method of measurement**
Using monitoring device

## Secondary outcomes

### 1

**Description**
Bradycardia(drop in heart rate below 50/ min)
**Timepoint**
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
**Method of measurement**
Using monitoring device

## Intervention groups

### 1

**Description**
Intervention group 1: In this group, granisetron at a dose of 3 mg equivalent to 3 ml is injected slow intravenously and once immediately before spinal anesthesia to eligible patients.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: In this group, ondansetron in a dose of 4 mg in a volume of 3 ml is injected slowly into intravenous patients immediately before spinal anesthesia.
**Category**
Treatment - Drugs

### 3

**Description**
Control group: In this group, 3 ml normal saline is injected slow intravenously and once immediately before spinal anesthesia to eligible patients.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Sadoughi Hospital
**Full name of responsible person**
Dr. Shekoufeh Behdad
**Street address**
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Yazd University of Medical Sciences
**Full name of responsible person**

Dr. Amirhooshang Mehrparvar

**Street address**
Central building of Yazd University of Medical Sciences, Bahonar Square.

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ah.mehrparvar@gmail.com

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Yazd 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**
Yazd University of Medical Sciences

**Full name of responsible person**
Dr Shekoufeh Behdad

**Position**
Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

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## Person responsible for scientific inquiries

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Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

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## Person responsible for updating data

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**Latest degree**
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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