

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing inguinal hernia repair surgery with spinal anesthesia

#### Protocol summary

##### Study aim

Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing inguinal hernia repair surgery with spinal anesthesia

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 130 patients. A table of random numbers is used for randomization.

##### Settings and conduct

The study will be performed on 130 patients referred to Shariati Hospital in Isfahan who are candidates for inguinal hernia repair surgery with spinal anesthesia. The study is double blind and both patients and drug injectors are unaware of the type of drug.

##### Participants/Inclusion and exclusion criteria

Entry requirements: The patient is a candidate for spinal hernia repair surgery by spinal anesthesia. The patient has consented to spinal anesthesia  
No entry conditions: The patient has a contraindication to spinal anesthesia. The patient has hypertension The patient has a history of heart disease. The patient has a history of migraine. The patient has a history of allergy to ondansetron. The patient has a history of taking any medication that changes blood pressure or heart rate.

##### Intervention groups

In the case group, 4 mg of onanestrone from Alborz company and in the control group, 4 ml of distilled water (placebo) will be injected by an anesthesiologist within 30 seconds. All patients will then be placed under spinal anesthesia from the L4-L5 or L3-L4 space with 15 mg of bupivacaine 0.5 using a 25-gauge needle. Immediately after spinal anesthesia and placing the patient in the open arch position, systolic pressure, diastolic blood pressure, moderate blood pressure and heart rate will be measured again and recorded in a questionnaire.

##### Main outcome variables

Systolic blood pressure Diastolic blood pressure Mean arterial pressure Heart rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110103005536N10**

Registration date: **2021-04-01, 1400/01/12**

Registration timing: **prospective**

Last update: **2021-04-01, 1400/01/12**

Update count: **0**

##### Registration date

2021-04-01, 1400/01/12

##### Registrant information

##### Name

Mohamadreza Rafiei

##### Name of organization / entity

Artesh University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8802 8933

##### Email address

mo\_rafiei@armyums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-18, 1400/01/29

##### Expected recruitment end date

2021-09-20, 1400/06/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing inguinal hernia repair surgery with spinal anesthesia

**Public title**

Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing surgery with spinal anesthesia

**Purpose**

Treatment

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

The patient is a candidate for spinal hernia repair surgery by spinal anesthesia The patient has consented to spinal anesthesia

**Exclusion criteria:**

The patient has a contraindication to spinal anesthesia. The patient has hypertension The patient has a history of heart disease The patient has a history of migraine The patient has a history of allergy to ondansetron The patient has a history of taking any medication that changes blood pressure or heart rate

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **130**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sample size in this study is 130 participants who will be studied by simple random sampling method. For this purpose, to place patients in the case or control group, we will use the function of generating random numbers in Excel software and with Depending on whether the number is even or odd, we place the sample in the case or control group. (Even numbers will be in the case group and odd numbers will be in the control group) also, in order to hide the random sequence in the participants, from the opaque envelopes sealed with random sequence (SNOSE) using the cards related to each group, based on the order of entry of the eligible participants in the study, the envelopes are opened in order. And the group assigned to that participant is identified.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is double blind and both the patient and the injector (outcome assessor) will be unaware of the contents of the syringe and only the syringe number will be recorded in the relevant checklist. The syringe may contain the drug or distilled water (placebo).

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Islamic Azad University, Najafabad Branch

**Street address**

Daneshgah Blvd.

**City**

Najaf abad

**Province**

Isfahan

**Postal code**

8514143131

**Approval date**

2020-01-01, 1398/10/11

**Ethics committee reference number**

IR.IAU.NAJAFABAD.REC.1399.011

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

Spinal anesthesia

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Systolic blood pressure

**Timepoint**

Before, during and after spinal anesthesia

**Method of measurement**

NIBP (non invasive blood pressure) monitoring

**2****Description**

Diastolic blood pressure

**Timepoint**

Before, during and after spinal anesthesia

### Method of measurement

NIBP (non invasive blood pressure) monitoring

### 3

#### Description

Mean arterial pressure

#### Timepoint

Before, during and after spinal anesthesia

#### Method of measurement

NIBP (non invasive blood pressure) monitoring

### 4

#### Description

Heart rate

#### Timepoint

Before, during and after spinal anesthesia

#### Method of measurement

Patient's monitoring

## Secondary outcomes

### 1

#### Description

Nausea and vomiting

#### Timepoint

After spinal anesthesia

#### Method of measurement

Clinical observation

### 2

#### Description

Chills

#### Timepoint

After the intervention

#### Method of measurement

Clinical observation

## Intervention groups

### 1

#### Description

Intervention group: After placing the patient on the operating table and before performing spinal anesthesia, systolic blood pressure, diastolic blood pressure, moderate blood pressure, using non-invasive measurement method, and heart rate, are measured using electrocardiogram monitoring and checked. The list will be recorded as the base parameters. Then, in the case group, 4 mg of ondansetron from Alborz company will be injected by an anesthesiologist within 30 seconds. Then, all patients will be placed under spinal anesthesia from the L4-L5 or L3-L4 space with 15 mg of bupivacaine 0.5 using a 25-gauge needle. Immediately after spinal anesthesia and placing the patient in the open arch position, systolic pressure, diastolic blood pressure, moderate blood pressure and heart rate will be measured again and recorded in a questionnaire. All of

the above parameters are measured and recorded immediately after anesthesia, Fifth minute, tenth minute, fifteenth minute, twentieth minute, twenty-fifth minute and thirty minutes after spinal anesthesia. In case of nausea during the operation, which is determined by asking the patient. This issue is recorded in the questionnaire. In case of vomiting, this issue is also recorded in the questionnaire. The occurrence of any shivering will also be recorded in the questionnaire.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: After placing the patient on the operating table and before performing spinal anesthesia, systolic blood pressure, diastolic blood pressure, moderate blood pressure, using non-invasive measurement method, and heart rate, are measured using electrocardiogram monitoring and checked. The list will be recorded as the base parameters. Then in the control group, 4 ml of distilled water (placebo) will be injected by an anesthesiologist in 30 seconds. Then, all patients will be placed under spinal anesthesia from the L4-L5 or L3-L4 space with 15 mg of bupivacaine 0.5 using a 25-gauge needle. Immediately after spinal anesthesia and placing the patient in the open arch position, systolic pressure, diastolic blood pressure, moderate blood pressure and heart rate will be measured again and recorded in a questionnaire. All of the above parameters are measured and recorded immediately after anesthesia, Fifth minute, tenth minute, fifteenth minute, twentieth minute, twenty-fifth minute and thirty minutes after spinal anesthesia. In case of nausea during the operation, which is determined by asking the patient. This issue is recorded in the questionnaire. In case of vomiting, this issue is also recorded in the questionnaire. The occurrence of any shivering will also be recorded in the questionnaire.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Shariati Hospital

##### Full name of responsible person

Dr. Mohammadreza Rafiei

##### Street address

First taajeddin St., Chaarbaagh Ave.

##### City

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##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University  
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Dr. Hamed Ghomi  
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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**  
Islamic Azad University  
**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**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammadreza Rafiei  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All research data can be shared after identifying individuals

**When the data will become available and for how long**

Start the access period after printing the results

**To whom data/document is available**

All researchers in the field of anesthesia and only by mentioning the source

**Under which criteria data/document could be used**

It can be used only for therapeutic and research purposes and by mentioning the source

**From where data/document is obtainable**

Dr. Mohammadreza Rafiei

**What processes are involved for a request to access data/document**

Send a request email to Dr. Rafiei and receive the data if the user approves

**Comments**