

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Effect of intravenous ondansetron in comparison with placebo on prevention of hypotension after spinal anesthesia in patients undergoing lower limb orthopedic surgery

#### Protocol summary

##### Study aim

Determination of the effect of intravenous ondansetron in the prevention of hypotension after spinal anesthesia in patients undergoing orthopedic surgery

##### Design

This trial will have a control group with parallel and double-blind groups, with restricted randomization and by the method of random allocation and concealment with sealed envelopes and phase 3 will be performed on 100 patients.

##### Settings and conduct

The study will be performed in the operating room of Peymaniyeh Hospital in Jahrom. The study will be double blind so that patients and researchers do not know which syringe will contain the drug.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates for orthopedic surgery by spinal anesthesia, individual satisfaction and age 18 to 65 years. Non-inclusion criteria: Patients with hypertension and cardiovascular problems, taking any medication that changes blood pressure or heart rate

##### Intervention groups

Intervention group: receives 4 mg of ondansetron before spinal anesthesia. Control group receives 4 mg of placebo.

##### Main outcome variables

Percentage of people with low blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201006048947N1**

Registration date: **2020-10-21, 1399/07/30**

Registration timing: **prospective**

Last update: **2020-10-21, 1399/07/30**

Update count: **0**

##### Registration date

2020-10-21, 1399/07/30

##### Registrant information

###### Name

Nasim Nabizadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 0022 3275

###### Email address

nassimnabizadeh@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of intravenous ondansetron in comparison with placebo on prevention of hypotension after spinal anesthesia in patients undergoing lower limb orthopedic surgery

##### Public title

The effect of ondansetron on the prevention of hypotension after spinal anesthesia

**Purpose**

Supportive

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

Candidates for orthopedic surgery by spinal anesthesia at Peymanieh Hospital in Jahrom Satisfaction of the person to participate in the study age between 18 to 65 years

**Exclusion criteria:**

Patients with hypertension weight more than 100 kg motion sickness cardiac and liver disease and migrain allery to ondansetron drugs using any drugs that change blood pressure or hear rate and any drugs that effects by serotonin receptor

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This clinical trial is performed in a simple randomization with individual randomization unit and in order to obtain equal sample sizes in the two groups, it is performed in a restricted randomization and by the method of random allocation rule, so that first the total sample size is determined (for example, 100 samples) and then we divide the set into group A and the set into group B, then 50 balls for intervention A and 50 balls for intervention B are placed in the lottery, then the balls are randomly drawn out without replacement. It is taken out of the container and the created sequence is recorded. To hide random allocation, opaque sealed envelopes with random sequences are used. After determining the random sequence, a number of envelopes are prepared and random sequences are recorded on the card and placed in the envelope. Envelopes are numbered sequentially, and when collecting samples, the envelopes are opened one by one and the assigned group is identified.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Before performing spinal anesthesia, an anesthesiologist inserts syringes, half of which contain ondansetron and the other half containing placebo, and the syringes are numbered, so neither the participant nor the clinical caregiver and the researcher knows which syringe is placebo and which one is the medicine.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Jahrom University of Medical Sciences

**Street address**

Jahrom University Of Medical science; Motahari street

**City**

Jahrom

**Province**

Fars

**Postal code**

7414846199

**Approval date**

2020-01-22, 1398/11/02

**Ethics committee reference number**

IR.JUMS.REC.1398.075

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

Hypotention induced by spinal anesthesia

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

Percentage of people with hypotension

**Timepoint**

Blood pressure measurement during the first 10 minutes, every 3 minutes and then every 5 minutes until the end of 30 minutes of spinal anesthesia

**Method of measurement**

Measurement with heart monitoring device

**Secondary outcomes****1****Description**

Percentage of people with decreased heart rate

**Timepoint**

during the first 10 minutes, every 3 minutes and then every 5 minutes until the end of 30 minutes of spinal anesthesia

### Method of measurement

Measuring heart rate with a heart rate monitor

## 2

### Description

Percentage of people with pruritus after spinal anesthesia

### Timepoint

Every 10 minutes after spinal anesthesia

### Method of measurement

by asking the patient

## 3

### Description

Percentage of people with nausea after spinal anesthesia

### Timepoint

Every 10 minutes after spinal anesthesia

### Method of measurement

by asking the patient

## Intervention groups

### 1

### Description

Intervention group: Patients are among the candidates for orthopedic surgery for spinal anesthesia who have no contraindications to spinal anesthesia and have been fasting for at least 8 hours receiving 300 mg of normal saline or ringer and 4 mg of ondansetron intravenously before spinal anesthesia during 30 seconds.

### Category

Other

### 2

### Description

Control group: Intervention group: Patients are among the candidates for orthopedic surgery for spinal anesthesia who have no contraindications to spinal anesthesia and have been fasting for at least 8 hours receiving 300 mg of normal saline or ringer and 4 mg of placebo intravenously before spinal anesthesia during 30 seconds.

### Category

Placebo

## Recruitment centers

### 1

### Recruitment center

#### Name of recruitment center

Peyanie hospital

#### Full name of responsible person

Nasim Nabizadeh

#### Street address

T the end of Valiye-e-asr street

#### City

Jahrom

### Province

Fars

### Postal code

7419886688

### Phone

+98 54 0023 0011

### Email

nassinabizadeh@gail.com

## Sponsors / Funding sources

### 1

### Sponsor

#### Name of organization / entity

Jahrom University of Medical Sciences

#### Full name of responsible person

Dr Kavoods Solhjo

#### Street address

At the end of Ostad Motahari avenue

#### City

Jahrom

#### Province

Fars

#### Postal code

7414846199

#### Phone

+98 54 0034 0405

#### Email

nassimnabizadeh@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

#### Full name of responsible person

Nasim Nabizadeh

#### Position

Intern

#### Latest degree

A Level or less

#### Other areas of specialty/work

General Practitioner

**Street address**

No. 26, Helal Ahmar avenue

**City**

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**Province**

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**Postal code**

7413718849

**Phone**

+98 54 0022 3275

**Fax****Email**

Nassimnabizadeh@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Nasim Nabizadeh

**Position**

Intern

**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Nasim Nabizadeh

**Position**

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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**

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

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

All data will be shareable

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

Access starts 6 months after the results are published

**To whom data/document is available**

Only for researchers working in academic institutions

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

Only for researchers working in academic institutions

**From where data/document is obtainable**

To the researcher named Nasim Nabizadeh by calling 00989364731778 Or the postal address of Jahrom, Helal Ahmar Street, 26th Alley with postal code 7413718849 Or email nassimnabizadeh@gmail.com

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

This data is available 6 months after the publication of the results and the applicant will have access to it up to one week after the announcement of the request.

**Comments**