

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparative study of intravenous Ondansetron and Dexamethasone Effects on Reducing the Incidence of PostSpinal Anesthesia Hypotension in Elderly Patients Undergoing Urologic Surgeries

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effect of preventive administration of two drugs (ondansetron and dexamethasone) on reducing hypotension and bradycardia in elderly patients undergoing spinal anesthesia.

##### Design

double blind randomized controlled trial on 120 patients who were Candidate for elective urology surgeries

##### Settings and conduct

120 patients ,attending Shahid Beheshti and Modarres Hospitals are divided into three groups . Group A: 4 mg Ondansetron, 5 minutes before S.A is injected . Group B: 5 minutes before spinal anesthesia, 8 mg of intravenous Dexamethasone is injected Group C: Medicine is not injected before S.A.. Blood pressure and heart rate monitoring is recorded in all 3 groups before & 30 minutes following the S.A

##### Participants/Inclusion and exclusion criteria

Inclusion  $\leq 65$  of age American Society of Anesthesiologists (ASA) physical status I, II EF>40% Patients who do not have a contraindication for spinal anesthesia (such as coagulation disorder, thrombocytopenia). Not allergic to local anesthetic No allergy to ondansetron or dexamethasone Not taking drugs related to steroids or serotonin (for example, selective serotonin reuptake inhibitors) Not suffering from uncontrolled cardiovascular, kidney, liver and thyroid diseases Exclusion Study confounding items such as: Occurrence of surgical complications such as bleeding, hemodynamic instability

##### Intervention groups

The patients are selected and randomly divided into 3 groups of 40 patients: First intervention group, Group A: 5 minutes before spinal anesthesia, 4 mg Ondansetron is injected intravenously Second intervention group Group B: 5 minutes before S A, 8 mg Dexamphetamine is

injected & the control group Group C: No medicine is injected before S.A.

##### Main outcome variables

Systolic and Diastolic blood pressure, Heart rate, Ondansetron, Dexamethasone, Atropine, Ephedrine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230513058164N1**

Registration date: **2023-05-18, 1402/02/28**

Registration timing: **retrospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

##### Registration date

2023-05-18, 1402/02/28

##### Registrant information

##### Name

Masoumeh Tork

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4424 7962

##### Email address

aban253@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-11, 1401/08/20

##### Expected recruitment end date

2023-02-19, 1401/11/30

**Actual recruitment start date**

2022-11-11, 1401/08/20

**Actual recruitment end date**

2023-02-19, 1401/11/30

**Trial completion date**

2023-02-19, 1401/11/30

**Scientific title**

The comparative study of intravenous Ondansetron and Dexamethasone Effects on Reducing the Incidence of PostSpinal Anesthesia Hypotension in Elderly Patients Undergoing Urologic Surgeries

**Public title**

The comparative study of intravenous Ondansetron and Dexamethasone effects on reducing the incidence of postspinal anesthesia hypotension in elderly patients undergoing urologic surgeries

**Purpose**

Prevention

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

65 years of age or more American Society of Anesthesiologists (ASA) physical status EF>40% Patients who do not have a contraindication for spinal anesthesia (such as coagulation disorder, thrombocytopenia ) Not allergic to local anesthetic No allergy to ondansetron or dexamethasone Not taking drugs related to steroids or serotonin (for example, selective serotonin reuptake inhibitors) Not suffering from uncontrolled cardiovascular, kidney, liver and thyroid diseases

**Exclusion criteria:**

Study Confounding Items Such as: Occurrence of Surgical Complications Such as Bleeding Hemodynamic Instability

**Age**From **65 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**Target sample size: **120**Actual sample size reached: **120****Randomization (investigator's opinion)**

Randomized

**Randomization description**

120 patients. are randomly assigned based on the inclusion and exclusion criteria, using the software of the website <http://www.Randomization.com> . Their information are registered and informed consent obtained. Based on the central randomization system , the patient is assigned to the study groups by contacting the randomization center . This is done by a hospital colleague not involved in other stages of the study .

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

.Patients are classified into three groups according to the randomization program and entered into the study according to the determined codes. In order to complete the study, the anesthesiologist assistant who is not participating in the study gives i.v. injections of Ondansetron or Dexamethasone in a 5 cc syringe preparation, 5 minutes prior to the spinal anesthesia. The patient, the caregivers of the operating room, the evaluator and the data analyst. are unaware of the type , dosage of drug injected.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Yasuj University of Medical Sciences

**Street address**

Shahid Motahhari Blvd

**City**

Yasuj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

7591741417

**Approval date**

2022-10-26, 1401/08/04

**Ethics committee reference number**

IR.YUMS.REC.1401.114

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

Post spinal hypotension in elderly patients

**ICD-10 code**

I95

**ICD-10 code description**

Hypotension

**2****Description of health condition studied**

Post Spinal Bradycardia

**ICD-10 code**

R00.1

**ICD-10 code description**

Bradycardia, unspecified

## Primary outcomes

### 1

#### Description

Systolic Blood Pressure

#### Timepoint

5 minutes before and 30 minutes following Spinal Anesthesia .

#### Method of measurement

Sphygmomanometer

### 2

#### Description

Diastolic Blood Pressure

#### Timepoint

5 minutes before and 30 minutes following Spinal Anesthesia

#### Method of measurement

Sphygmomanometer

### 3

#### Description

Heart Rate

#### Timepoint

5 minutes before and 30 minutes following Spinal Anesthesia Procedure

#### Method of measurement

Pulse Oximeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention Group A : Ondansetron Amp 4mg ,slow iv , Single Dose. 5 minutes prior to Spinal Anesthesia.

#### Category

Prevention

### 2

#### Description

Intervention Group B: Dexamethasone Amp 8mg iv , Single Dose , 5 minutes prior to Spinal Anesthesia,.

#### Category

Prevention

### 3

#### Description

The control group consists of 40 patients who are randomly selected and receive a study participation code. They receive no injectable drug before spinal anesthesia.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yasuj Shahid Beheshti Hospital

##### Full name of responsible person

Dr Mehrdad Bagheri

##### Street address

Shahid Montazeri

##### City

Yasuj

##### Province

Kohgiluyeh-va-Boyer-Ahmad

##### Postal code

759174857

##### Phone

+98 74 3322 1813

##### Email

pr@yu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Modarres Hospital

##### Full name of responsible person

Dr Saeed Alipour

##### Street address

Saadatabad

##### City

Tehran

##### Province

Tehran

##### Postal code

3438319987

##### Phone

+98 21 2207 4087

##### Email

modarres@sbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Dr MohammadAmin Gholamnezhad

##### Street address

Shahid Motahhari

##### City

Yasuj

##### Province

Kohgiluyeh-va-Boyer-Ahmad

##### Postal code

7591794857

##### Phone

+98 74 3333 7220

##### Email

info@myreshte.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Masoumeh Tork

**Position**

Resident of Anesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**Province**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Masoumeh Tork

**Position**

Resident of Anesthesiology

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Masoumeh Tork

**Position**

Anesthesiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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1463755184

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**Fax**

**Email**

aban253@gmail.com

## 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**

Data recording sheets, Result Charts, Analytical Charts available in article link and research text

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

Available while article is accessible

**To whom data/document is available**

Research team

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

Upon formal request

**From where data/document is obtainable**

Researcher

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

Formal written request

**Comments**