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 ≤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 crietria, 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
Kohgilouyeh-va-Boyrahmad
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
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Kohgilouyeh-va-Boyrahmad
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759174857
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2

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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

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