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
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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  
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
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2
Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1
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Email

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
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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
<table>
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<th>Under which criteria data/document could be used</th>
<th>What processes are involved for a request to access data/document</th>
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<td>From where data/document is obtainable</td>
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