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)

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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 desease 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 secends.
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 plasbo intravenously before spinal anesthesia during 30 secends.
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Dr Kavoos Solhjo
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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
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

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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
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