Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing inguinal hernia repair surgery with spinal anesthesia

Protocol summary

Study aim

Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing inguinal hernia repair surgery with spinal anesthesia

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 130 patients. A table of random numbers is used for randomization.

Settings and conduct

The study will be performed on 130 patients referred to Shariati Hospital in Isfahan who are candidates for inguinal hernia repair surgery with spinal anesthesia. The study is double blind and both patients and drug injectors are unaware of the type of drug.

Participants/Inclusion and exclusion criteria

Entry requirements: The patient is a candidate for spinal hernia repair surgery by spinal anesthesia. The patient has consented to spinal anesthesia No entry conditions: The patient has a contraindication to spinal anesthesia. The patient has hypertension The patient has a history of heart disease. The patient has a history of migraine. The patient has a history of allergy to ondansetron. The patient has a history of taking any medication that changes blood pressure or heart rate.

Intervention groups

In the case group, 4 mg of onanestrone from Alborz company and in the control group, 4 ml of distilled water (placebo) will be injected by an anesthesiologist within 30 seconds. All patients will then be placed under spinal anesthesia from the L4-L5 or L3-L4 space with 15 mg of bupivacaine 0.5 using a 25-gauge needle. Immediately after spinal anesthesia and placing the patient in the open arch position, systolic pressure, diastolic blood pressure, moderate blood pressure and heart rate will be measured again and recorded in a questionnaire.

Main outcome variables

Systolic blood pressure Diastolic blood pressure Mean arterial pressure Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110103005536N10**
Registration date: **2021-04-01, 1400/01/12**
Registration timing: **prospective**

Last update: **2021-04-01, 1400/01/12**
Update count: **0**

Registration date

2021-04-01, 1400/01/12

Registrant information

Name

Mohamadreza Rafiei

Name of organization / entity

Artesh University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 8933

Email address

mo_rafiei@armyums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-18, 1400/01/29

Expected recruitment end date

2021-09-20, 1400/06/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing inguinal hernia repair surgery with spinal anesthesia

Public title
Investigating the effect of intravenous ondansetron on arterial blood pressure changes and heart rate in patient undergoing surgery with spinal anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is a candidate for spinal hernia repair surgery by spinal anesthesia The patient has consented to spinal anesthesia
Exclusion criteria:
The patient has a contraindication to spinal anesthesia. The patient has hypertension The patient has a history of heart disease The patient has a history of migraine The patient has a history of allergy to ondansetron The patient has a history of taking any medication that changes blood pressure or heart rate
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample size in this study is 130 participants who will be studied by simple random sampling method. For this purpose, to place patients in the case or control group, we will use the function of generating random numbers in Excel software and with Depending on whether the number is even or odd, we place the sample in the case or control group. (Even numbers will be in the case group and odd numbers will be in the control group) also, in order to hide the random sequence in the participants, from the opaque envelopes sealed with random sequence (SNOSE) using the cards related to each group, based on the order of entry of the eligible participants in the study, the envelopes are opened in order. And the group assigned to that participant is identified.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind and both the patient and the injector (outcome assessor) will be unaware of the contents of the syringe and only the syringe number will be recorded in the relevant checklist. The syringe may contain the drug or distilled water (placebo).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Najafabad Branch
Street address
Daneshgah Blvd.
City
Najaf abad
Province
Isfehan
Postal code
8514143131
Approval date
2020-01-01, 1398/10/11
Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1399.011

Health conditions studied

1

Description of health condition studied
Spinal anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
Before, during and after spinal anesthesia
Method of measurement
NIBP (non invasive blood pressure) monitoring

2

Description
Diastolic blood pressure
Timepoint
Before, during and after spinal anesthesia

Method of measurement
NIBP (non invasive blood pressure) monitoring

3

Description
Mean arterial pressure
Timepoint
Before, during and after spinal anesthesia
Method of measurement
NIBP (non invasive blood pressure) monitoring

4

Description
Hearth rate
Timepoint
Before, during and after spinal anesthesia
Method of measurement
Patient's monitoring

Secondary outcomes

1

Description
Nausea and vomiting
Timepoint
After spinal anesthesia
Method of measurement
Clinical observation

2

Description
Chills
Timepoint
After the intervention
Method of measurement
Clinical observation

Intervention groups

1

Description
Intervention group: After placing the patient on the operating table and before performing spinal anesthesia, systolic blood pressure, diastolic blood pressure, moderate blood pressure, using non-invasive measurement method, and heart rate, are measured using electrocardiogram monitoring and checked. The list will be recorded as the base parameters. Then, in the case group, 4 mg of ondansetron from Alborz company will be injected by an anesthesiologist within 30 seconds. Then, all patients will be placed under spinal anesthesia from the L4-L5 or L3-L4 space with 15 mg of bupivacaine 0.5 using a 25-gauge needle. Immediately after spinal anesthesia and placing the patient in the open arch position, systolic pressure, diastolic blood pressure, moderate blood pressure and heart rate will be measured again and recorded in a questionnaire. All of the above parameters are measured and recorded immediately after anesthesia,. Fifth minute, قه tenth minute, fifteenth minute, twentieth minute, twenty-fifth minute and thirty minutes after spinal anesthesia. In case of nausea during the operation, which is determined by asking the patient. This issue is recorded in the questionnaire. In case of vomiting, this issue is also recorded in the questionnaire. The occurrence of any shivering will also be recorded in the questionnaire.
Category
Treatment - Drugs

2

Description
Control group: After placing the patient on the operating table and before performing spinal anesthesia, systolic blood pressure, diastolic blood pressure, moderate blood pressure, using non-invasive measurement method, and heart rate, are measured using electrocardiogram monitoring and checked. The list will be recorded as the base parameters. Then in the control group, 4 ml of distilled water (placebo) will be injected by an anesthesiologist in 30 seconds. Then, all patients will be placed under spinal anesthesia from the L4-L5 or L3-L4 space with 15 mg of bupivacaine 0.5 using a 25-gauge needle. Immediately after spinal anesthesia and placing the patient in the open arch position, systolic pressure, diastolic blood pressure, moderate blood pressure and heart rate will be measured again and recorded in a questionnaire. All of the above parameters are measured and recorded immediately after anesthesia,. Fifth minute, قه tenth minute, fifteenth minute, twentieth minute, twenty-fifth minute and thirty minutes after spinal anesthesia. In case of nausea during the operation, which is determined by asking the patient. This issue is recorded in the questionnaire. In case of vomiting, this issue is also recorded in the questionnaire. The occurrence of any shivering will also be recorded in the questionnaire.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariati Hospital
Full name of responsible person
Dr. Mohammadreza Rafiei
Street address
First taajeddin St., Chaarbaagh Ave.
City
Esfahan
Province
Isfehan
Postal code
4538481737
Phone
+98 31 3627 2001

Email
mo_rafiei@armyums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Hamed Ghomi
Street address
Daneshgah Blvd.
City
Najafabad
Province
Isfehan
Postal code
8514143131
Phone
+98 31 4229 2929
Email
mo_rafiei@armyums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Artesh University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Rafiei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Aja univercity of medical science, Etemadzadeh St., West Fatemi Ave.,
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
mo_rafiei@armyums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mohamadreza Rafiei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Aja univercity of medical science, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8802 8933
Fax
+98 31 1263 1587
Email
mo_rafiei@armyums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Rafiei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Aja univercity of medical science, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8802 8933

Fax
+98 31 1263 1587
Email
mo_rafiei@armyums.ac.ir

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
All research data can be shared after identifying individuals
When the data will become available and for how long
Start the access period after printing the results
To whom data/document is available
All researchers in the field of anesthesia and only by mentioning the source
Under which criteria data/document could be used
It can be used only for therapeutic and research purposes and by mentioning the source
From where data/document is obtainable
Dr. Mohammadreza Rafiei
What processes are involved for a request to access data/document
Send a request email to Dr. Rafiei and receive the data if the user approves
Comments