Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of prophylactic injection of doses of 4 and 8 mg of intravenous Ondansetron on nausea and itching after spinal injection of Fentanyl in spinal anesthesia, in lower limb orthopedic surgery

Protocol summary

Study aim

Comparison of the effect of prophylactic injection of doses of 4 and 8 mg of intravenous Ondansetron on nausea and itching after spinal injection of Fentanyl in spinal anesthesia, in lower limb orthopedic surgery

Design

A controlled, parallel-group, triple-blind, randomized, phase 2 clinical trial on 90 patients. The lottery is used for randomization

Settings and conduct

This is a three-blind randomized clinical trial that will be conducted on 90 patients candidate for orthopedic surgery under spinal anesthesia in Kashani Hospital, Isfahan. After the approval of the ethics committee and obtaining the consent of the patients, the patients are randomly assigned into groups, in each group the desired intervention is applied and the clinical symptoms of the patient are recorded. The researcher who records the patient's symptoms, the analysts who collect the data analyzed during the study, and the patients did not know the type of intervention applied in each group, so they were all blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 years, ASA anesthesia class I and II, candidate for lower limb orthopedic surgery under spinal anesthesia, and consent to participate in the study. Non-Inclusion criteria: addiction to cigarettes, narcotics, and psychotropic substances, allergy to any of the drugs used, presence of skin infection at the injection site, anti-nausea use in the last 24 hours, pregnancy and breastfeeding

Intervention groups

Intervention group A: Patients in this group receive 8 mg of ondansetron (equivalent to 4 ml) intravenously 30 minutes after spinal. Intervention group B: Patients in this group receive 4 mg of ondansetron (equivalent to 4 ml) intravenously 30 minutes after spinal. Control group C: Patients in this group receive 4 mg of 4 ml of distilled water intravenously 30 minutes after spinal

Main outcome variables

nausia, itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N47**
Registration date: **2022-10-12, 1401/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-12, 1401/07/20**
Update count: **0**

Registration date

2022-10-12, 1401/07/20

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3212 3543

Email address

behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of prophylactic injection of doses of 4 and 8 mg of intravenous Ondansetron on nausea and itching after spinal injection of Fentanyl in spinal anesthesia, in lower limb orthopedic surgery

Public title
Investigating the effect of Ondansetron on nausea and itching caused by spinal Fentanyl injection
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18 to 65 years old Anesthesia class I and II according to ASA criteria Candidate for lower limb surgery under spinal anesthesia Informed consent to enter the study
Exclusion criteria:
History of smoking, drug and psychedelic addiction Allergy to any anesthetic drugs, Ondansetron and fentanyl History of coagulation disorders High ICP Pregnancy or breastfeeding Skin infection at the injection site Anti-nausea use in the last 24 hours
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a simple randomized clinical trial in which patients entered the study groups by lottery; The medicines and placebo are placed in sealed, opaque, and similar form packets coded. Each code is also written on a piece of paper, folded, and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box; The pocket with the same number is the intervention that will apply to him. This process continues till the number of patients will reach the desired one.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a three-way blind clinical trial; In this way, the researcher who records the patient's symptoms is different from the person who injects the drug and has no knowledge of the type of drug and is blind. The analysts who analyze the data collected during the study also don't know the type of intervention in any group and they are blind. Even though the patients are included in the study, they do not know the type of intervention and are blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-07-31, 1401/05/09
Ethics committee reference number
IR.MUI.MED.REC.1401.182

Health conditions studied

1

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

Primary outcomes

1

Description
Severity of nausea
Timepoint
Every 5 minutes after spinal until 15 minutes and then every 15 minutes until the end of the 4th hour
Method of measurement
Nausea and vomiting severity behavioral scale questionnaire

2

Description

Itching scale

Timepoint

Every 5 minutes after spinal until 15 minutes and then every 15 minutes until the end of the 4th hour

Method of measurement

Itching severity scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: In this group of eligible patients, after receiving 5 ml/kg of Crystalloid fluid, they are placed on the surgical bed and cardiorespiratory monitoring is connected. Then they are subjected to spinal anesthesia with 25 µg of Fentanyl manufactured by Caspin Pharmaceutical Company and 12.5 mg of Markain manufactured by Aburihan Pharmaceutical Company. Then 30 minutes after the spinal, they receive 8 mg of Ondansetron manufactured by Elixir pharmaceutical company intravenously. The patient's symptoms including blood pressure, heart rate, and breathing rate are checked and recorded regularly every 5 minutes for 15 minutes and then every 15 minutes until the end of the fourth hour.

Category

Prevention

2

Description

Intervention group A: In this group of eligible patients, after receiving 5 ml/kg of Crystalloid fluid, they are placed on the surgical bed and cardiorespiratory monitoring is connected. Then they are subjected to spinal anesthesia with 25 µg of Fentanyl manufactured by Caspin Pharmaceutical Company and 12.5 mg of Markain manufactured by Aburihan Pharmaceutical Company. Then 30 minutes after the spinal, they receive 4 mg of Ondansetron manufactured by Elixir pharmaceutical company intravenously. The patient's symptoms including blood pressure, heart rate, and breathing rate are checked and recorded regularly every 5 minutes for 15 minutes and then every 15 minutes until the end of the fourth hour.

Category

Prevention

3

Description

Control group C: In this group of eligible patients, after receiving 5 ml/kg of Crystalloid fluid, they are placed on the surgical bed and cardiorespiratory monitoring is connected. Then they are subjected to spinal anesthesia with 25 µg of Fentanyl manufactured by Caspin Pharmaceutical Company and 12.5 mg of Markain manufactured by Aburihan Pharmaceutical Company. Then 30 minutes after the spinal, they receive 4 ml of distilled water manufactured by Elixir pharmaceutical company intravenously. The patient's symptoms including blood pressure, heart rate, and breathing rate are checked and recorded regularly every 5 minutes for 15 minutes and then every 15 minutes until the end of the fourth hour.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Behzad Nazemoroaya

Street address

Kashani St

City

Isfahan

Province

Isfehan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

behzad_nazem@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezar Jarib

City

اصفهان

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Sepide Hasani
Position
Anesthesiology resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
sepideh.hassani@yandex.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Behzad Nazem roaya
Position
Professor assistant of Anesthesia and Intensive carentensive care
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
behzad_nazem@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Leyla Rafiei
Position
Nurse Anesthetist
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
Leylarafiei943@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available