Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of ephedrine, ketamine, ondansetron and atropine drugs to prevent nausea and vomiting during and after surgery in patients under spinal anesthesia for lower limb fracture repair

Protocol summary

Study aim

The effect of ephedrine, ketamine, ondansetron and atropine on nausea and vomiting during and after surgery under spinal anesthesia.

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 2-3 on 128 patients, the patients were randomized based on the block random pattern.

Settings and conduct

Patients are hospitalized for at least one day before surgery and will fast for 8 hours. Upon entering the operating room, an intravenous line is established for the patient and through it they receive 10 ml per kg of Ringer's serum. Before the spinal anesthesia, the patients will receive 4 groups of medicine. In order to equalize the volume of intervention medicine in all groups, after calculating the desired dose, it will be brought to 5 ml with distilled water and administered intravenously. The frequency and severity of nausea and vomiting, the degree of sedation and the amount of metoclopyramide will be recorded by the student. The study will be designed in a double-blind manner.The patient, the data recorder, and the analyst will not know about the grouping.

Participants/Inclusion and exclusion criteria

Inclusion cditeria: age 18-75 years ohd; both genders; ASA class 1 and 2; lower limb fracture repair surgery under spinal anesthesia. Failure to enter: history of drug addiction; history of allergies: neuromuscular diseases: cardiomyopathy: coagulation disease: underlying disease.

Intervention groups

Group 1: 5 mg of ephedrine. Group 2: 100 micrograms of atropine. Group 3: 8 mg of ondansetron. Group 4: Ketamine at the rate of 0.3 mg per kg

Main outcome variables

Vomiting score in recovery, 2, 4, 6, 12, and 24 hours after surgery Occurrence of nausea during recovery, 2, 4, 6, 12, and 24 hours after surgery. Severity of nausea during recovery, 2, 4, 6, 12, and 24 hours after surgery RAMSAY score in recovery and 1, 2 and 4 hours after the operation Taking Metoclopyramide within 24 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230713058769N1**
Registration date: **2023-07-29, 1402/05/07**
Registration timing: **prospective**

Last update: **2023-07-29, 1402/05/07**
Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Mohammadreza Hasani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-05-21, 1403/03/01

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

Scientific title
Comparison of the effect of ephedrine, ketamine, ondansetron and atropine drugs to prevent nausea and vomiting during and after surgery in patients under spinal anesthesia for lower limb fracture repair

Public title
Comparison of the effect of ephedrine, ketamine, ondansetron and atropine drugs to prevent nausea and vomiting during and after surgery in patients under spinal anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-75 years old Both genders ASA class 1 and 2 Lower limb fracture repair surgery under spinal anesthesia Consent to participate in the study
Exclusion criteria:
History of drug addiction History of seasonal allergies and allergies to any of the drugs used in this study Presence of neuromuscular diseases Presence of cardiomyopathy Presence of coagulopathy Presence of an underlying disease
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into 4 groups based on the balanced block randomization pattern and the size of the blocks will be 8. The randomization is done by the consultant professor using the online program at https://www.sealedenvelope.com/. Hiding the random chain is done by the method of opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be designed in a double-blind manner. The method of blinding is that the anesthesiologist prepares the drugs and the anesthetist performs the spinal anesthesia. A student who is responsible for recording information in certain time intervals. Also, the groups are sent to the statistician using coding, and the analyst does not know about the grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Vice chancellor of Research, Prophet Azam University Complex, Arak University of Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2023-06-27, 1402/04/06
Ethics committee reference number
IR.ARAKMU.REC.1402.087

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Vomiting score according to the vomiting score table
Timepoint
In recovery, 2, 4, 6, 12 and 24 hours after the operation
Method of measurement
Physical examination

2

Description
Number of times nausea occurs
Timepoint
In recovery, 2, 4, 6, 12 and 24 hours after the operation

Method of measurement
Physical examination

3

Description
Severity of nausea according to visual analogue scale
Timepoint
In recovery, 2, 4, 6, 12 and 24 hours after the operation
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
The degree of sedation according to the RAMSAY SCORE
Timepoint
In recovery and 1, 2 and 4 hours after the operation
Method of measurement
RAMSAY SCORE

2

Description
Dosage of Metoclopramide
Timepoint
Within 24 hours after the operation
Method of measurement
Patient file

Intervention groups

1

Description
Intervention group 1: Before spinal anesthesia, they will receive 5 mg of ephedrine (Sterop belgium pharmaceutical company). In order to equalize the volume of the intervention drug in all groups, after calculating the desired dose, it will be brought to 5 ml with distilled water. And it is administered intravenously.
Category
Treatment - Drugs

2

Description
Intervention group 2: Before spinal anesthesia, they will receive 100 micrograms of atropine (Caspin Pharmaceutical Company, Rasht Supply - Iran). In order to equalize the volume of the intervention drug in all groups, after calculating the desired dose, it will be brought to 5 ml with distilled water. And it is administered intravenously.
Category
Treatment - Drugs

3

Description
Intervention group 3: Before spinal anesthesia, they will receive 8 mg of ondansetron (Alborz Daru Pharmaceutical Company). In order to equalize the volume of the intervention drug in all groups, after calculating the desired dose, it will be brought to 5 ml with distilled water. And it is administered intravenously.
Category
Treatment - Drugs

4

Description
Intervention group 4: Before the spinal anesthesia, they will receive 0.3 mg per kg of ketamine (Exir pharmaceutical company - Iran). In order to equalize the volume of the intervention drug in all groups, after calculating the desired dose, it will be brought to 5 ml with distilled water. And it is administered intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamoddin Modir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Davood Hekmat Po
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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor of Research of Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamoddin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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Person responsible for updating data

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Position

Associate professor

Latest degree

Specialist

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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