

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 criteria: age 18-75 years old; 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)

##### Phone

+98 86 3477 7490

##### Email address

mohammadrezahasani7899@gmail.com

##### 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

##### **Street address**

Valiasr Hospital, Valiasr Square

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3814957558

##### **Phone**

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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

##### **Street address**

Vice chancellor of Research, Prophet Azam University Complex, Basij Square

##### **City**

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research@arakmu.ac.ir

**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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Valiasr Hospital, Valiasr Square

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

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**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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Dr Hesamoddin Modir

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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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