

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of adding low dose of epinephrine with intrathecal bupivacaine and fentanyl on hemodynamic stability of patients undergoing orthopedic lower limb surgery:A Clinical trial study

#### Protocol summary

##### Study aim

The effect of adding low dose of epinephrine with intrathecal bupivacaine and fentanyl on hemodynamic stability of patients undergoing orthopedic lower limb surgery.

##### Design

This study will be a double-blind randomized clinical trial with parallel groups on 128 patients referred to Peymaniyeh Hospital in Jahrom who are undergoing orthopedic lower limb surgery. Patients participating in the study will be divided into two groups by tossing coins.

##### Settings and conduct

Patients referred to Peymaniyeh Hospital in Jahrom who will undergo orthopedic surgery of the lower extremities will be included in the study. Patients participating in the study will be divided into two groups by tossing coins. The study participant, researcher, and data collector will be unaware of the type of drug being used.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients referred to Peymaniyeh Hospital in Jahrom who underwent lower limb orthopedic surgery and expressed their consent to participate in the study. Non-entry conditions: includes patients who do not have hemodynamic stability and suffer from acute and chronic pain.

##### Intervention groups

Intervention group 1: They receive 0.2 mg epinephrine + 25 micrograms fentanyl + 10 mg bupivacaine intrathecally. Intervention group 2: 10 mg bupivacaine + 25 µg fentanyl intrathecally.

##### Main outcome variables

Blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210415050976N4**

Registration date: **2021-06-13, 1400/03/23**

Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**

Update count: **0**

##### Registration date

2021-06-13, 1400/03/23

##### Registrant information

##### Name

navid kalani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5433 6085

##### Email address

k.navid@juma.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-02, 1400/07/10

##### Expected recruitment end date

2021-12-31, 1400/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of adding low dose of epinephrine with

intrathecal bupivacaine and fentanyl on hemodynamic stability of patients undergoing orthopedic lower limb surgery:A Clinical trial study

#### Public title

The effect of adding low dose of epinephrine with intrathecal bupivacaine and fentanyl on hemodynamic stability of patients undergoing orthopedic lower limb surgery:A Clinical trial study

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Anesthesia class one and two

##### Exclusion criteria:

Diabetes History of cardiovascular disease Shortness of breath Kidney or liver disease

#### Age

From **18 years** old to **80 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **128**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients participating in the present study were randomly divided into two groups by tossing coins.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

For blinding in the present study, the double-blind method is used so that 1- the person reviewing the results and 2- the person performing the injections do not know which patient received epinephrine.

#### 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

Ethics Committee of Jahrom University of Medical

Sciences

##### City

Jahrom

##### Province

Fars

##### Postal code

7167758256

##### Approval date

2021-03-16, 1399/12/26

##### Ethics committee reference number

IR.JUMS.REC.1399.155

### Health conditions studied

#### 1

##### Description of health condition studied

Hemodynamics in lower limb orthopedic patients

##### ICD-10 code

G89.18

##### ICD-10 code description

Other acute postprocedural pain

### Primary outcomes

#### 1

##### Description

Blood pressure

##### Timepoint

Before prescribing the studied drug, before spinal anesthesia, after anesthesia and then every half hour until the end of surgery and during recovery will be measured and recorded.

##### Method of measurement

Monitoring

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: They receive 0.2 mg epinephrine + 25 micrograms fentanyl + 10 mg bupivacaine intrathecally and in a single dose.

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: 10 mg bupivacaine + 25 micrograms fentanyl intrathecally and receive a single dose.

##### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Peymaniyeh Hospital of Jahrom city

**Full name of responsible person**

Navid Kalani

**Street address**

Jahrom, Shahid Motahari Boulevard, Peymanieh Hospital

**City**

jahrom

**Province**

Fars

**Postal code**

71677251542

**Phone**

+98 71 3525 5652

**Email**

Navidkalani@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Solh joo Kavous

**Street address**

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

**City**

jahrom

**Province**

Fars

**Postal code**

7167758256

**Phone**

+98 71 2536 5231

**Email**

solhjok@yahoo.com

**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**

Navid Kalani

**Position**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

**Street address**

Jahrom, Shahid Motahari Boulevard

**City**

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**Postal code**

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**Phone**

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**Email**

k.navid@jums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Navid Kalani

**Position**

Research Expert

**Latest degree**

Master

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## Person responsible for updating data

#### Contact

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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