

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

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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

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Person responsible for scientific inquiries

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Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

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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