

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Effect of Adding Dexmedetomidine and fentanyl to bupivacaine on pain and shivering in patients undergoing lower extremity orthopedic surgery using spinal anesthesia

Protocol summary

Study aim

Comparing the Effect of Adding Dexmedetomidine and fentanyl to bupivacaine on pain and shivering in patients undergoing lower extremity orthopedic surgery using spinal anesthesia

Design

This study will perform a two-way blind randomized clinical trial with parallel groups on 60 patients referred to Peymaniyeh Hospital in Jahrom who are undergoing lower limb orthopedic surgery. Patients participating in the study will be divided into three groups by throwing dice.

Settings and conduct

Patients referred to Jahrom's Peymaniyeh Hospital, who will undergo lower limb orthopedic surgery, will be included in the study. 10 ug fentanyl + 15 mg bupivacaine. Control group: 15 mg bupivacaine will be divided. The study participant, the researcher, and the data collector will be unaware of the type of medication being taken.

Participants/Inclusion and exclusion criteria

All patients referred to Peymaniyeh Hospital in Jahrom who have undergone lower limb orthopedic surgery and express their satisfaction to participate in the study and do not have the criteria to leave the study.

Intervention groups

Interventional group 1: 5 Microgram of dexamethasone + 15 mg of bupivacaine taken intrathecal. The intervention group receives 2: 10 mg of fentanyl + 15 mg of bupivacaine taken intrathecal. Control group: receiving 15 mg of bupivacaine taken intrathecal.

Main outcome variables

Pain, chills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130926014779N4**

Registration date: **2020-05-29, 1399/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-29, 1399/03/09**

Update count: **0**

Registration date

2020-05-29, 1399/03/09

Registrant information

Name

Navid Kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5426 4192

Email address

k.navid@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-06-24, 1399/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Adding Dexmedetomidine and

fentanyl to bupivacaine on pain and shivering in patients undergoing lower extremity orthopedic surgery using spinal anesthesia

Public title

the Effect of Adding Dexmedetomidine and fentanyl to bupivacaine on pain and shivering in patients undergoing lower extremity orthopedic surgery using spinal anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Anesthesia class one and two

Exclusion criteria:

History of cardiovascular disease
History of narcotic use
Diabetes
Patients who suffered severe pain during the operation and had to undergo general anesthesia

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in the study were divided into three groups by throwing dice

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding in the present study, a double-blind method is used in a way that (1) the person who will review the results and (2) the person who performs the injections are unaware of which patients have received dexmedetomidine ,fentanil and bupivacaine alone.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Jahrom University of Medical

Sciences

Street address

School of medicine, Motahhari Blvd, Jahrom

City

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Province

Fars

Postal code

716775243

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.JUMS.REC.1399.011

Health conditions studied

1

Description of health condition studied

Pain and chills in orthopedic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

1, 2, 6, 12 and 24 hours after surgery

Method of measurement

Visual scale of pain

2

Description

chills

Timepoint

1, 2, 6, 12 and 24 hours after surgery

Method of measurement

Based on the Crossley division

Secondary outcomes

1

Description

Symptoms of hemodynamics

Timepoint

Before prescribing the drug under study, before spinal anesthesia, after anesthesia, and then every half hour until the end of surgery and during recovery

Method of measurement

By the device for measuring hemodynamic symptoms

2

Description

Nausea-vomiting

Timepoint

1, 2, 6, 12 and 24 hours after surgery

Method of measurement

questionnaire

Intervention groups**1****Description**

Interventional group 1: 5 ug of dexamethasone + 15 mg of bupivacaine taken intrathecally

Category

Treatment - Drugs

2**Description**

Intervention group 2: 10 ug fentanyl + 15 mg bupivacaine taken intrathecally.

Category

Treatment - Drugs

3**Description**

Control group: receiving 15 mg of bupivacaine intrathecally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Peymanieh Hospital, Jahrom city

Full name of responsible person

Navid Kalani

Street address

Jahrom, Shahid Motahhari Boulevard, Peymaniyeh Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Solh Ju Kavos

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Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom

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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 employee

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Research employee

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information. "

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available