

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of Dexmedetomidine and Fentanyl as Adjuvant to intrathecal Ropivacaine in Lower Limb Orthopedic Procedures

Protocol summary

Maximum level of sensory block, Blood pressure, Heart rate, Oxygen saturation, Postoperative pain

Study aim

Comparison of the effect of adding dexmedetomidine or fentanyl to intrathecal ropivacaine on sensory and motor characteristics and analgesia after orthopedic lower limb surgery

Design

90 patients undergoing lower limb orthopedic surgery are divided into three groups by block randomization method. Patients in the three groups were injected with 4.5 ml of ropivacaine with 5 mg dexmedetomidine in 5 ml normal saline, 4.5 ml ropivacaine + 25 mg fentanyl in 5 ml normal saline and 4.5 ml ropivacaine 5%, respectively. Isobarics were administered in 5 cc normal saline every 15 minutes. Hemodynamic parameters, postoperative pain intensity every 15 minutes, and time to sensory and motor block arrival were also determined in three groups.

Settings and conduct

This study was performed on patients undergoing lower extremity orthopedic surgery at Alzahra Hospital, Isfahan, Iran. This study is a double blind study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Weight less than 100 kg and Candidate Orthopedic Lower Limb Surgery and patient consent to participate in the study. Exclusion criteria included: Chronic pain report lasting more than 6 months, drug or ropivacaine sensitivity, fentanyl and dexmedetomidine, prohibition of spinal anesthesia, history of long-term drug use, or NSAIDs, or disease It is chronic.

Intervention groups

In the first group: 4.5 ml ropivacaine 3% isobaric + 5 mg dexmedetomidine is injected in 0.5 cc normal saline. In the second group: 4.5 ml Ropivacaine 3% isobaric + 25 mg fentanyl is injected in 0.5 ml normal saline. In the third group: 4.5 ml ropivacaine 5% isobaric intrathecal is injected in 0.5 ml of normal saline.

Main outcome variables

Time to reach sensory block, Time to motor block,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N41**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **prospective**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14

Expected recruitment end date

2020-09-19, 1399/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Dexmedetomidine and Fentanyl as Adjuvant to intrathecal Ropivacaine in Lower Limb Orthopedic Procedures

Public title
Comparison of the effect of adding dexmedetomidine or fentanyl to ropivacaine on sensory and motor characteristics and analgesia after orthopedic lower limb surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Weight less than 100 kg Patient undergoing lower extremity orthopedic surgery
Exclusion criteria:
Pregnancy History of addiction or smoking, drugs and alcohol liver disease cardiovascular disease Chronic pain report lasting more than 6 months Drug sensitivity or ropivacaine, fentanyl and dexmedetomidine contraindication of spinal anesthesia Long-term drug history or opioid and NSAIDs

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 90 patients undergoing lower limb orthopedic surgery were randomly divided into three groups of 30 each. Random allocation of patients between the three groups is done using random allocation software. At first the total sample size is entered into the software and then the number of study groups is entered. In software output, numbers 1 to 90 are randomly presented in three separate columns, according to which patients are divided into three groups according to the time of inclusion and as listed above to reach the required number in each group

Blinding (investigator's opinion)
Double blinded

Blinding description
The study was conducted in a double-blind manner and patients and researchers were uninformed with the type of drug administered. The drugs are drawn and coded on a similar syringe by an operating room staff member who is not involved in the study and provided to the plan administrator for injection.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Research faculty, Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan

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Approval date

2020-01-19, 1398/10/29

Ethics committee reference number

IR.MUI.REC.1396.3.666

Health conditions studied

1

Description of health condition studied

Sensory and motor nerve blocks

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Time to start sensory block

Timepoint

After the intrathecal injection of the anesthetic drug

Method of measurement

Sensory testing with no sensation of tingling with Nidel No. 23 is evaluated as subcutaneous stimulation.

Secondary outcomes

1

Description

Blood pressure

Timepoint

Every 15 minutes during surgery and recovery

Method of measurement

Pulse Oximeter

2**Description**

Heart rate

Timepoint

Every 15 minutes during surgery and recovery

Method of measurement

Pulse Oximeter

3**Description**

postoperative pain

Timepoint

Every 15 minutes in recovery and every 2 hour in ward

Method of measurement

With using visual Analog Scale. The criterion is a line between zero to ten and zero in the sense of no pain and ten being the most severe equivalent of the pain experienced by the patient. With this concept, the patient is asked to indicate their current pain intensity on line.

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

Intervention group: injection of 4.5 ml ropivacaine% isobaric + 5 micg dexmedetomidine in 5 ml normal slain

Category

Prevention

2**Description**

Intervention group: Injection of 4.5 ml of isobaric ropivacaine 3% + 25 mg fentanyl in 5 ml normal slain

Category

Prevention

3**Description**

Intervention group: Injection of 4.5 ml isobaric ropivacaine 3% in 5 ml normal normal slain

Category

Prevention

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

Alzahra hospital

Full name of responsible person

Mohamad javad Hoseini

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

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mohamad javad Hoseini

Position

Resident of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

The plan is owned by the government agency and cannot be shared.

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