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

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 salin, 4.5 ml ropivacaine + 25 mg fentanyl in 5 ml normal salin and 4.5 ml ropivacaine 5%, respectively. Isobarics were administered in 5 cc normal salin 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 salin. In the second group: 4.5 mlRopivacaine 3% isobaric + 25 mg fentanyl is injected in 0.5 ml normal salin. In the third group: 4.5 ml ropivacaine 5% isobaric intrathecal is injected in 0.5 ml of normal salin.

Main outcome variables

Time to reach sensory block, Time to motor block, Maximum level of sensory block, Blood pressure, Heart rate, Oxygen saturation, Postoperative pain

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

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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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

City

Isfahan

Province

Isfehan

Postal code

8434193474

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
Mohamadjavad 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
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Person responsible for updating data

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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