

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of Marcaine / Dexmedetomidine versus Marcaine / Fentanyl on the sensory motor block in unilateral spinal anesthesia of patients undergoing lower limb orthopedic surgery

Protocol summary

Study aim

comparison the effect of Marcaine / Dexmedetomidine versus Marcaine / Fentanyl on the sensory motor block in unilateral spinal anesthesia of patients undergoing lower limb orthopedic surgery

Design

Patients will be randomized (randomized list with PASS software) divided into two groups of BF and BD. Each group consists of 18 patients. In the BF group, marcaine and fentanyl are used, and in the BD group, marcaine and dexmedetomidine are used for unilateral spinal anesthesia.

Settings and conduct

This randomized clinical trial was performed on 36 patients undergoing unilateral orthopedic surgeries in one of the patients at Ghaem Hospital in Mashhad, Iran. In the group BF; mg7.5 marcaine (0.5% hyperbaric) and fentanyl 10 µg and in the BD group; 7.5 mg marcaine(0.5% hyperbaric) and 5 mg dexmedetomidine will be injected

Participants/Inclusion and exclusion criteria

Patients with ASA class I and II who were older than 18 years old entered to the study patients who had high intracranial pressure, infection in the site of block , coagulopathy, corticospinal tract disease , sensory-disabling diseases, neuropathy, and a history of discopathy were excluded.

Intervention groups

The effect of Marcaine / Dexmedetomidine versus Marcaine / Fentanyl on the sensory motor block in unilateral spinal anesthesia

Main outcome variables

The duration of the sensory-motor block (min); The onset of the effect of the sensory-motor block (min); the frequency of urinary retention; the hemodynamic status (heart rate, systolic and diastolic blood pressure); the frequency of nausea and vomiting; The frequency of

itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190510043545N1**

Registration date: **2019-08-14, 1398/05/23**

Registration timing: **retrospective**

Last update: **2019-08-14, 1398/05/23**

Update count: **0**

Registration date

2019-08-14, 1398/05/23

Registrant information

Name

seyed javad purafzali firuzabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3728 2267

Email address

sjvdpurafzali@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Marcaine / Dexmedetomidine versus Marcaine / Fentanyl on the sensory motor block in unilateral spinal anesthesia of patients undergoing lower limb orthopedic surgery

Public title

The effect of Marcaine / Dexmedetomidine versus Marcaine / Fentanyl on the sensory motor block in unilateral spinal anesthesia of patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for the unilateral lower limb orthopedic surgery and at least 18 years old ASA class I,II

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized (randomized list with PASS software) divided into two groups of BF and BD.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study. Patients are not aware of the type of drug used, and the person who are checked the symptoms does not know the type of medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreishi building , Daneshgah ave , Mashhad , Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

ir.mums.rec 1395.285

Health conditions studied

1

Description of health condition studied

unilateral spinal anesthesia of patients undergoing lower limb orthopedic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The duration of the sensory-motor block (min);

Timepoint

Every 5 minutes to 30 minutes and then every 15 minutes until the end of the operation is recorded. In the recovery, it is recorded at the time of entry and every 15 minutes until complete removal of the sensory motor block.

Method of measurement

Check motor level based on bromage scale and sensory level with pin prick test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the BD group, Marcaine and Dexmedetomidine are used for unilateral spinal anesthesia.

Category

Treatment - Drugs

2

Description

Control group: Control group: In the BF group, marcaine and fentanyl are used for unilateral spinal anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital , Mashhad , Iran

Full name of responsible person

Mohamad Alipour

Street address

Ahmad Abad Blvd , Mashhad , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah Blvd , Mashhad , Iran

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohamad Alipour

Position

Associate professor of anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Resident

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Medical doctor

Other areas of specialty/work

Anesthesiology

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Individual data of the participants after the collection and analysis is published as a article and report.

When the data will become available and for how long

Since 2019 and after the publication of the results

To whom data/document is available

All people who need our study results.

Under which criteria data/document could be used

For further studies, they can use the results of this study.

From where data/document is obtainable

Seyed Javad Purafzali Firuzabadi

sjvdpurafzali@yahoo.com

What processes are involved for a request to access data/document

In an email, the activity and study that needs the results of this study is explained, after the review is sent.

Comments