

# 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3840 0000

**Email**

sjvdpurafzali@yahoo.com

## 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Email**

tafaghodim@mums.ac.ir

**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

**Street address**

Ahmad Abad Blvd , Mashhad , Iran

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## Person responsible for scientific 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 updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Javad Purafzali Firuzabadi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Yaqut6 , Shahid sadeqi27 ave, Mashhhad , Iran

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**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 3728 2267

**Fax****Email**

sjvdpurafzali@yahoo.com

**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**