

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Efficacy of intrathecal midazolam in strengthening the analgesic effect of intrathecal fentanyl in patients undergoing lower limb surgery

#### Protocol summary

##### Summary

Objective: Clinical trial of evaluation the effect of intrathecal midazolam in combination with fentanyl in strengthening analgesic effect in the lower limb surgery. Design of the study: randomization using random permuted blocks, convenience sampling, double-blind, single-center, phase II trial. Study population: all patients of lower limb surgery with ASA PS I and II. Main inclusion criteria: age limitation 20-60 years; candidates of lower limb surgery with ASA PS I and II. Main exclusion criteria: contraindications to intrathecal analgesia; history of chronic pains; addiction; NSAID usage 12 hours prior to surgery. Sample size: 90. Interventions: First group: intravenous infusion of 3 cc of 0.5% marcaine plus 0.7 cc 0.09% normal saline; second group: intravenous infusion of 3 milligrams of 0.5% marcaine plus 25 micrograms phentanyl plus 0.2 cc 0.09% normal saline; third group: intravenous infusion of 3 cc of 0.5% marcaine in combination with 25 micrograms phentanyl and 1 milligrams midazolam. Intervention time: before the operation. Outcomes: duration of sensory nerve block; duration of motor block.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017030732923N1**

Registration date: **2017-04-21, 1396/02/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-21, 1396/02/01

##### Registrant information

##### Name

Sima Davarpanah

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5799

##### Email address

dr.davarpanah@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

##### Expected recruitment start date

2016-09-21, 1395/06/31

##### Expected recruitment end date

2017-09-22, 1396/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of intrathecal midazolam in strengthening the analgesic effect of intrathecal fentanyl in patients undergoing lower limb surgery

##### Public title

Evaluation the effect of intrathecal midazolam in combination with fentanyl in strengthening analgesic effect in the lower limb surgery

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Main inclusion criteria: age limitation 20-60 years; candidates of lower limb surgery with ASA PS I and II. Main exclusion criteria: contraindications to intrathecal

analgesia; history of chronic pains; addiction; NSAID usage 12 hours prior to surgery.

#### Age

From **20 years** old to **60 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

##### Street address

Ethics Committee of Zahedan University of Medical Sciences, Zahedan University of Medical Sciences, Dr.Hesabi Square, Zahedan

##### City

Zahedan

##### Postal code

#### Approval date

2016-09-21, 1395/06/31

#### Ethics committee reference number

IR.ZAUMS.REC.1395.31

## Health conditions studied

### 1

#### Description of health condition studied

Lower limb surgery

#### ICD-10 code

Y83

#### ICD-10 code description

Surgical operation and other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

## Primary outcomes

### 1

#### Description

Duration of sensory nerve block

#### Timepoint

Two heures, four heures, eight heures, 12 heures and 24 heures after surgery

#### Method of measurement

Sensory evaluation of patients with needle based on the time in minutes

### 2

#### Description

duration of motor block

#### Timepoint

Two heures, four heures, eight heures, 12 heures and 24 heures after surgery

#### Method of measurement

Evaluation of lower extremity mobility through mbs2 based on the time in minutes

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First group: intravenous infusion of 3 cc of 0.5% marcaine plus 0.7 cc of 0.09% normal saline

#### Category

Treatment - Drugs

### 2

#### Description

Second group: intravenous infusion of 3 cc of 0.5% marcaine plus 25 micrograms phentanyl plus 0.2 cc 0.09% normal saline

#### Category

Treatment - Drugs

### 3

#### Description

Third group: intravenous infusion of 3 cc of 0.5% marcaine in combination with 25 micrograms phentanyl and 1 milligrams of midazolam

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ali-ebn Abi Taleb Hospital, Zahedan

**Full name of responsible person**

Sima Davarpanah

**Street address**

Operation room, Zahedan Ali-ebn Abi Talib Hospital,  
Salamat Blvd, Dr.Hesabi Sq., Zahedan

**City**

Zahedan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Zahedan University of  
Medical Sciences

**Full name of responsible person**

Mohsen Taheri

**Street address**

Vice chancellor for research, Zahedan University of  
Medical Sciences, Zahedan

**City**

Zahedan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Zahedan University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Sima Davarpanah

**Position**

Anesthesiology Residence

**Other areas of specialty/work**

**Street address**

Operation room, Ali-ebn Abi Taleb Hospital, Salamat  
Blvd, Dr.Hesabi Sq., Daneshgah Ave., Zahedan

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**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr. Masoum Khoshfetrat

**Position**

Associate Professor of General anaesthesia

**Other areas of specialty/work**

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## Person responsible for updating data

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**Other areas of specialty/work**

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**Phone**

00

**Fax**

**Email**

Dr.davarpanah@zaums.ac.ir

**Web page address**

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*