

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

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Email address

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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

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Person responsible for scientific inquiries

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Dr. Masoum Khoshfetrat

Position

Associate Professor of General anaesthesia

Other areas of specialty/work

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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