

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Analgesic Effect of Adding Midazolam and Fentanyl to Intrathecal Bupivacaine 0.05% in Patients with Orthopedic Surgery of Lower Limbs

Protocol summary

Summary

The current protocol was aimed to compare analgesic effect of adding Midazolam and Fentanyl to Intrathecal Bupivacaine 0.05% in patients with orthopedic surgery of lower limbs. Patients needed anesthesia divided into three groups including Midazolam (M), Fentanyl (F), and Normal saline (N). Seventy five patients conducted in this survey. This study was double blind that anesthesiologist who was unaware of the contents of the syringe. Also, the specialist assessing pain was not aware of patients assigned to groups. Patients were allocated in to three groups using block allocation method. All patients were provided by Normal Saline prior to induction and venipuncture was also done from upper limb distal using vein catheter no 18 for all groups. Groups M, F, and N, received respectively 0.5 mg Midazolam, 25 µg Fentanyl, and 0.5 ml Normal Saline. Inclusion criteria were as follow: 1) people aged 18-65 years that categorized into class 1 and 2 based on America Society of Anesthesiologists (ASA). Exclusion criteria were considered as: 1): patients with substance abuse, patients with symptoms of neuropathy, and lack of appropriate sensory level after performing the spinal anesthesia. To measure pain, Verbal analogue Scale was used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061810340N9**

Registration date: **2016-09-25, 1395/07/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-25, 1395/07/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Science

Expected recruitment start date

2015-10-17, 1394/07/25

Expected recruitment end date

2016-05-22, 1395/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic Effect of Adding Midazolam and Fentanyl to Intrathecal Bupivacaine 0.05% in Patients with Orthopedic Surgery of Lower Limbs

Public title

Analgesic Effect of Adding Midazolam and Fentanyl to Intrathecal Bupivacaine 0.05%

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: people aged 18-65 years that categorized into class 1 and 2 based on America Society of Anesthesiologists (ASA); Exclusion criteria : rejection

of patients with substance abuse, patients with symptoms of neuropathy, and lack of appropriate sensory level after performing the spinal anesthesia.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Golestan University of Medical Science

Street address

4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

City

Gorgan

Postal code

Golestan

Approval date

2015-10-16, 1394/07/24

Ethics committee reference number

IR.Goums.REC.1395.105

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

M79.6

ICD-10 code description

Pain in limb

Primary outcomes

1

Description

Duration of analgesia

Timepoint

After intervention

Method of measurement

Duration of analgesia

Secondary outcomes

1

Description

Hemodynamic Change

Timepoint

Before Intervention, 30 ,60 and 90 minutes after intervention

Method of measurement

Sphygmomanometer, Pols oximeter

2

Description

Chills

Timepoint

After intervention

Method of measurement

Observation

3

Description

Nausea

Timepoint

After intervention

Method of measurement

Observation

4

Description

Vomiting

Timepoint

After intervention

Method of measurement

Observation

Intervention groups

1

Description

15 mg of bupivacaine 0.5% (3 cc) with 0.5 mg of midazolam

Category

Placebo

2

Description

15 mg of bupivacaine 0.5% (3 cc) with fentanyl 25 microgram (µg)

Category

Placebo

3

Description

15 milligram (mg) of bupivacaine 0.5% (equivalent to 3 cc) with 0.5 milliliter (ml) of normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Hospital

Full name of responsible person

Payam Sorodi

Street address

5 Azar Hospital, 5 Azar Street, Gorgan City, Golestan Province

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University of Medical Science

Full name of responsible person

Homeira Kodam

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4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

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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

Golestan University of Medical Science

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

Golestan University of Medical Science

Full name of responsible person

Homeira Khodam

Position

Research and Technolgy Managment

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Mohamma Aryaie

Position

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Other areas of specialty/work

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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