Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Name
Mohammad Aryaie
Name of organization / entity
Golestan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 911 277 1798
Email address
aryaie@goums.ac.ir

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
Street address
4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan
City
Gorgan
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
Street address
4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan
City
Gorgan
Postal code
Phone
+98 17 3242 4377
Fax
Email
homeira_khoddam@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Golestan University of Medical Science
Full name of responsible person
Payam Sorodi
Position
Anesthesia Specialist
Other areas of specialty/work
Street address
4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan
City
Gorgan
Postal code
Phone
+98 17 3242 4377
Fax
Email
payam202@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Golsestan University of Medical Sciences
Full name of responsible person
Mohamma Aryaie
Position
MSc in Epidemiology
Other areas of specialty/work

Street address
4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan
City
Gorgan
Postal code
Phone
+98 17 3242 4377
Fax
Email
Aryaiem2009@yahoo.com
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