Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of intrathecal fentanyl on bispectral index during spinal anesthesia in patients with lower limb orthopedic surgery.

Protocol summary

Summary

Objective: The addition of opioids to local anesthetics in spinal anesthesia modulates some aspects of anesthesia and analgesia. In this study, the effect of adding intrathecal fentanyl on bispectral index (BIS) during spinal anesthesia will be evaluated. Materials and Methods: According to prospective clinical trial studies, the patients undergoing lower limb orthopedic surgery will randomly be divided into 2 groups of control and intervention ones. Inclusion criteria will be physical status class I from the perspective of American Society of Anesthesiologists; planned for lower limb orthopedic surgery undergoing spinal anesthesia; and lack of opioid addiction. Exclusion criteria will be spinal anesthesia contraindications; any unusual complications including a lot of bleeding during surgery; and prolonged surgery. The control group will receive 12.5 mg of 0.5% hyperbaric bupivacaine (Astrazeneca) (HBB), while the intervention group will receive 12.5 mg of HBB plus 20 µg of intrathecal fentanyl (Abureyhan). After the induction of spinal anesthesia, a bispectral index (BIS) monitor will be connected and baseline values will be recorded for each patient. BIS, vital signs, nausea and vomiting and shivering will also be recorded for each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080627677N4**
Registration date: **2016-08-28, 1395/06/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

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Name of organization / entity
Urmia University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Urmia University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrathecal fentanyl on bispectral index during spinal anesthesia in patients with lower limb orthopedic surgery.

Public title

Clinical trial the effect of intrathecal opioid on bispectral index in patient with lower limb orthopedic surgery under spinal anesthesia.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: physical status class I from the

perspective of America society of Anesthesiologists; lower limb orthopedic surgery with spinal anesthesia; Lack of opioid addiction Exclusion criteria: spinal anesthesia contraindications; any unusual complications including a lot of bleeding during surgery; prolonged surgery

Age
No age limit

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Patients will be divided into two groups by random number table .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Urmia University of Medical Sciences

Street address
Emergent Street, Resalat Avenue, Urmia

City
Urmia

Postal code
5714783734

Approval date
2015-08-06, 1394/05/15

Ethics committee reference number
ir.umsu.rec.1394.273

Health conditions studied

1

Description of health condition studied
sedation in spinal anesthesia

ICD-10 code
T88.7

ICD-10 code description
Unspecified adverse effect of drug or medicament

Primary outcomes

1

Description
level of consciousness

Timepoint
Bispectral index will be recorded at baseline and 5, 10, 15, 30, 45 and 60 minutes after spinal injection.

Method of measurement
Bispectral Index Monitoring

Secondary outcomes

1

Description
Mean Arterial Blood Pressure

Timepoint
Mean Arterial Pressure will be recorded 5, 10, 15, 30, 45 and 60 minutes after spinal injection at baseline.

Method of measurement
None Invasive Blood Pressure

2

Description
Heart Rate

Timepoint
Heart Rate will be recorded 5, 10, 15, 30, 45 and 60 minutes after spinal injection at baseline.

Method of measurement
Electrocardiogram

Intervention groups

1

Description
Intervention group: will receive hyperbaric bupivacaine with intrathecal fentanyl. In sitting position lumbar puncture will done using a 25 gauge needle (Exel) into the subarachnoid space L3-L4 in the midline just cephalad. After cerebrospinal fluid aspiration, 2.5 ml of 0.5% hyperbaric bupivacaine (Astrazeneca) plus 20 µg fentanyl (Abureyhan) will inject.

Category
Diagnosis

2

Description
Control group: will receive alone hyperbaric bupivacaine .In sitting position lumbar puncture will done using a 25 gauge needle (Exel) into the subarachnoid space L3-L4 in the midline just cephalad. After cerebrospinal fluid aspiration, 2.5 ml of 0.5% hyperbaric bupivacaine (Astrazeneca) will inject.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomeini Hospital, C operating room

Full name of responsible person
Shahryar Sane,Assistant Professor, Anesthesiologist

Street address
Modarres Avenue, Ershad Avenue

City
Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Urmia University of Medical Sciences

Full name of responsible person
Shahryar Sane

Street address
Ershad avenue, Imam Khomeini Hospital, Department of Anesthesiology

City
Urmia

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 of Urmia 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
Urmia University of Medical Sciences

Full name of responsible person
Shahryar Sane

Position
Assistant Professor, anesthesiologist

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