Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

The effect of hyperbaric bupivacaine dosage on the incidence and severity of early complications after spinal anesthesia for orthopedic surgeries

Protocol summary

Study aim

The effect of hyperbaric bupivacaine dose on the incidence and severity of early complications after spinal anesthesia for orthopedic surgeries

Design

Clinical trial has three intervention groups, with parallel groups, double-blind, randomized, phase 2-3 on 60 patients. The Rand function of the Excel software was used for randomization.

Settings and conduct

60 adults aged 18 to 60 years old candidates for lower limb orthopedic surgeries in Shohada hospital based on inclusion criteria, will be randomly divided into three distinct groups A, B, and C, defined on the basis of hyperbaric bupivacaine 0.5% injection dosage into the intrathecal space [C: 20mg, B: 15mg, A: 12.5mg] and sampling will be double-blind. Patients and the person injecting the drug and filling out the questionnaires are unaware of the dose of the injected drug. Spinal anesthesia will be performed with a 23G Quincke Spinal needle in a sitting position from the L4-L5 space. Immediately after the injection, patients will be in the supine position, and vital signs and incidence of nausea and vomiting will be recorded at regular intervals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 60 years; Orthopedic lower limb surgeries; Having an indication for spinal anesthesia; Patients with ASA class I and II Exclusion criteria: Patient discontent with spinal anesthesia; Uncontrolled blood pressure; Uncontrolled diabetes; History of previous neurological problems; Presence of coagulation problems; Hypersensitivity to anesthetics; Septicemia or local infection at the site of needle entry

Intervention groups

Three groups named A, B and C are defined based on the dose of bupivacaine 0.5% hyperbaric injection into the intrathecal space. 12.5 mg, 15 mg and 20 mg of bupivacaine will be injected intrathecally, respectively.

Main outcome variables

Heart rate; Blood pressure; Oxygen saturation; Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160202026328N7**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-10, 1400/10/20**
Update count: **0**

Registration date

2022-01-10, 1400/10/20

Registrant information

Name

Masoud Parish

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 5842

Email address

parishm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of hyperbaric bupivacaine dosage on the incidence and severity of early complications after spinal anesthesia for orthopedic surgeries

Public title
The effect of hyperbaric bupivacaine dosage on the incidence and severity of early complications after spinal anesthesia for orthopedic surgeries
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 60 years Orthopedic lower limb surgeries Having an indication for spinal anesthesia Patients with ASA class I and II
Exclusion criteria:
Patient discontent with spinal anesthesia Uncontrolled blood pressure in the patient Uncontrolled diabetes in the patient History of previous neurological problems in the patient Presence of coagulation problems in the patient Hypersensitivity to anesthetics Septicemia or local infection at the site of needle entry
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be selected based on inclusion and exclusion criteria and will be randomly assigned to treatment groups using permuted blocks. For randomization, the Rand function of Excel software is used, in which the randomization unit is individuals. Sampling will be double-blind and all the desired variables will be recorded based on a pre-prepared questionnaire.
Blinding (investigator's opinion)
Double blinded
Blinding description
The anesthesiologist, who is in charge of the patient's anesthesia management, injects the drug through coded syringes that have already been prepared by the thesis owner. So that anesthesiologist is unaware of the injected drug to patient during injection. The anesthesia nurse, who is responsible for collecting information and variables from the patient and is unaware of the type of prescribed drug, fills the checklist during surgery and recovery. The patient is also unaware of the type of Injecting drug.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Faculity of Medicine, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-11-29, 1400/09/08
Ethics committee reference number
IR.TBZMED.REC.1400.820

Health conditions studied

1

Description of health condition studied
Complications of spinal anesthesia
ICD-10 code
T88.59
ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description
Blood pressure
Timepoint
Immediately after becoming supine and then at intervals of 5 minutes to half an hour and then every 15 minutes to an hour.
Method of measurement
In millimeters of mercury using a non-invasive method of measuring blood pressure by the device.

2

Description
Heart rate
Timepoint
Immediately after becoming supine and then at intervals of 5 minutes to half an hour and then every 15 minutes to an hour.
Method of measurement
Beat Per minute using a non-invasive heart rate monitor

3

Description
Hypoventilation and hypoxia
Timepoint
Immediately after becoming supine and then at intervals of 5 minutes to half an hour and then every 15 minutes to an hour
Method of measurement
Monitoring the respiratory rate per minute and measuring oxygen saturation by pulse oximetry

4

Description
Nausea and vomiting
Timepoint
Immediately after becoming supine and then at intervals of 5 minutes to half an hour and then every 15 minutes to an hour.
Method of measurement
Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Three groups named A, B and C, which are defined based on the dose of hyperbaric bupivacaine 0.5% injection into the intrathecal space. In all three groups, in order to homogenize the interventions, the temperature of the solutions is the same and spinal anesthesia will be performed in sitting position and in sterile condition with a 23G Quincke spinal needle from the L4-L5 space. The surgeries will be the same and with a fixed duration. Immediately after the injection, patients will be in the supine position, and vital signs and incidence of nausea and vomiting will be recorded at regular intervals. For intervention group A, 12.5 mg of bupivacaine will be injected to intrathecal space.
Category
Treatment - Drugs

2

Description
Intervention group B: 15 mg of hyperbaric bupivacaine 0.5% will be injected to intrathecal space.
Category
Treatment - Drugs

3

Description
Intervention group C: 20 mg of hyperbaric bupivacaine 0.5% will be injected to intrathecal space.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Hospital
Full name of responsible person
Dr. Masoud Parish
Street address
Shohada Hospital, Golshahr Avenue, Yaghchian, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5167846171
Phone
+98 41 3385 5842
Email
parishm@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
Street address
Research Vice-Chancellor, Third floor, the headquarter building No 2, Tabriz University of Medical Sciences, Golgasht street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Masoud Parish
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shohada Hospital, Gholshahr Avenue, Yaghchian, tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5167846171
Phone
+98 41 3385 5842
Fax
+98 41 3385 3171
Email
parishm@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Masoud Parish
Position
Anesthesiologist/Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shohada Hospital, Golshahr Avenue, Yaghchian, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5167846171
Phone
+98 41 3385 5842
Fax
Email
parishm@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Masoud Parish
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shohada Hospital, Gholshahr Avenue, Yaghchian, tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5167846171
Phone
+98 41 3385 5842
Fax
+98 41 3385 3171
Email
parishm@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data can be shared after making peoples unrecognizable.
When the data will become available and for how

long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academia and people in industry.

Under which criteria data/document could be used

There are no specific restrictions on the use of data or documentation.

From where data/document is obtainable

Dr .Masoud Parish Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran Phone: +98 413 3341994, masoudparish@yahoo.com

What processes are involved for a request to access data/document

Applicants will have access to the data from the present study by sending an email to the responsible author for a maximum of one week.

Comments