

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

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget 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

Faculty 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

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Shohada Hospital, Golshahr Avenue, Yaghchian, Tabriz, Iran

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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

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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

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

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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