

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

A comparative evaluation of perioperative complications of intrathecal sufentanil and fentanyl in combination with bupivacaine and bupivacaine alone for lower limb orthopedic surgery

Protocol summary

Summary

Objective: A comparative evaluation of perioperative complications of intrathecal sufentanil and fentanyl in combination with bupivacaine and bupivacaine alone for lower limb orthopedic surgery. Inclusion criteria: adults aged 18-65 years; American Society of Anesthesiology classification of 1-2; No contraindication for spinal anesthesia; No history of opium abuse; No history of neurologic, neuromuscular or psychological disorders; no history of allergic reaction to local anesthetic Exclusion criteria: request for analgesic drugs or opioids during spinal anesthesia; need for general anesthesia during operation; pregnancy Target population: all adults aged 18-65 years candidate for lower extremities orthopedic surgery in Hazrat Rasoul Medical Center and Firouzgar hospital. Sample size: there are three groups in the study; we will assign 30 patients for each group randomly. Interventions: in first group we will administrate intrathecally 15mg Bupivacaine 0.5% with 5 microgram sufentanil , in second group we will administrate intrathecally 15mg Bupivacaine 0.5% with 25 microgram fentanyl and in the control group we will administrate intrathecally 15mg Bupivacaine 0.5% with 0.5 ml Distilled water. This study will be finalized in 12 months in 2010-2011. Primary outcome: mean arterial pressure and hemodynamic changes will be evaluated in all three groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209045822N2**
Registration date: **2012-10-14, 1391/07/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-14, 1391/07/23

Registrant information

Name

Valiollah Hassani

Name of organization / entity

Department of Anesthesiology, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6650 9059

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valiollah_hassani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative evaluation of perioperative complications of intrathecal sufentanil and fentanyl in combination with bupivacaine and bupivacaine alone for lower limb orthopedic surgery

Public title

Effect of adding fentanyl and sufentanil to bupivacaine in spinal anesthesia in perioperative complications of orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: adults aged 18-65 years; American Society of Anesthesiology classification of 1-2; No contraindication for spinal anesthesia; No history of opium abuse; No history of neurologic, neuromuscular or psychological disorders; no history of allergic reaction to local anesthetic
Exclusion criteria: request for analgesic drugs or opioids during spinal anesthesia; need for general anesthesia during operation; pregnancy

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: **90**

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

Tehran University of Medical Sciences

Street address

Room 501, 5th Floor, Central Office of Tehran

University of Medical Sciences, Keshavarz Bolvard

City

Tehran

Postal code

Approval date

2012-05-27, 1391/03/07

Ethics committee reference number

203/130/91/5

Health conditions studied

1

Description of health condition studied

lower limb bone fracture

ICD-10 code

M84

ICD-10 code description

Disorders of continuity of bone

Primary outcomes

1

Description

Mean Arterial Pressure

Timepoint

every 2 min til 20 min, then every 5 min until transferring the patient to the recovery then every 15 min until transferring to the ward.

Method of measurement

Electronic sphygmometer

Secondary outcomes

1

Description

O2 Saturation

Timepoint

every 2 min til 20 min, then every 5 min until transferring the patient to the recovery then every 15 min until transferring to the ward.

Method of measurement

pulse oximetry

2

Description

Heart rate

Timepoint

every 2 min til 20 min, then every 5 min until transferring the patient to the recovery then every 15 min until transferring to the ward.

Method of measurement

pulse oximetry

3

Description

Maximum height of sensory block

Timepoint

10 min after intervention

Method of measurement

physical examination

4

Description

Ephedrin administration

Timepoint

when blood pressure decrease to 20% of base or below 100mmhg

Method of measurement

yes/ no

5

Description

Bradycardia

Timepoint

when Heart rate decreases below 60 per min.

Method of measurement

pulse oximetry

Intervention groups

1

Description

sufentanil Group: we will administrate intrathecally 15mg Bupivacaine 0.5% (Bupivacaine®, Milan Co, Italy) with 5 microgram Sufentanil (Sufenta, Janssen-Cilag, India)

Category

Treatment - Drugs

2

Description

Fentanyl group: we will administrate intrathecally 15mg Bupivacaine 0.5% (Bupivacaine®, Milan Co, Italy) with 25 microgram fentanyl (Fentanyl, Abureyhan, Iran)

Category

Treatment - Drugs

3

Description

Control group: we will administrate intrathecally 15mg Bupivacaine 0.5% (Bupivacaine®, Milan Co, Italy) with 0.5 ml Distilled water

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Hospital

Full name of responsible person

Valiollah Hassani

Street address

Niyayesh St, Sattarkhan St.

City

Tehran

2

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Maryam Hajiashrafi

Street address

Valiasr Sq., Behafarin St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Ghodrati

Street address

Firouzgar Hospital, Behafarin St. ,Valiasr Sq.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Valiollah Hassani

Position

Professor of Anesthesiology

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