

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of adding different doses of epinephrine to the fentanyl and bupivacaine solution in spinal anesthesia in lower limb orthopedic surgeries with tourniquet

Protocol summary

Summary

Sixty patients undergoing lower limb orthopedic surgery with tourniquet are studied in this randomized clinical trial. Inclusion criteria: ASA class 1, 2 and aged between 20-65. Exclusion criteria: emergency surgeries; patient dissatisfaction; infection of injection site; high intracranial pressure; coagulopathy; difficulties to communicate with patient in order to evaluate them during surgery; addiction; allergies to spinal anesthetic drugs. Patients are randomly allocated into one of these two groups: A= 12-15 milligram bupivacaine+ 25 microgram fentanyl+ 0.1 milligram epinephrine. B= 12-15 milligram bupivacaine+ 25 microgram fentanyl+ 0.3 milligram epinephrine. Spinal anesthetic is administered in lumbar space in sitting position. Then patients are located in supine position. Patients will receive 0.01-0.03 milligram/kilogram midazolam as sedative. These parameters will be measured 5, 10, 20, 30, 60, 90, 120 minutes after spinal and in post anesthesia care unit: sensory block level will be evaluated by pinprick method and time of reaching to the highest level and 4 dermatome backsliding will be evaluated. Motor block level will be evaluated by bromage scale (0= patient is able to move the hip, knee and ankle; 1= patient is unable to move the hip but is able to move the knee and ankle; 2= patient is unable to move the hip and knee but is able to move the ankle; 3= patient is unable to move the hip, knee and ankle) . Heart rate, blood pressure, nausea and vomiting, apnea, shivering and suffering from pain during surgery and in post anesthesia care unit are recorded and will be treated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505193829N5**

Registration date: **2016-02-16, 1394/11/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-16, 1394/11/27

Registrant information

Name

Pejman Pourfakhr

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sina Hospital

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of adding different doses of epinephrine to the

fentanyl and bupivacaine solution in spinal anesthesia in lower limb orthopedic surgeries with tourniquet

Public title

Effects of adding different doses of epinephrine to the fentanyl and bupivacaine solution in spinal anesthesia in lower limb orthopedic surgeries with tourniquet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: candidates of lower limb orthopedic surgeries with tourniquet with ASA class I and II; ages between 20-65 Exclusion criteria: emergency surgeries; patient dissatisfaction; infection of injection site; high intracranial pressure; coagulopathy; difficulties to communicate with patient in order to evaluate them during surgery; addiction; allergies to spinal anesthetic drugs

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Sealed Envelope

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Science

Street address

Taleqani St. Qods St. Enghelab Sq.

City

Tehran

Postal code

Approval date

2015-07-20, 1394/04/29

Ethics committee reference number

IR.TUMS.REC.1394.387

Health conditions studied

1

Description of health condition studied

spinal anesthesia in lower limb orthopedic surgeries

ICD-10 code

XIII

ICD-10 code description

M22, M23

Primary outcomes

1

Description

Sensory Block

Timepoint

After spinal up to reaching to the highest sensory block level and 4 dermatome backsliding

Method of measurement

Pinprick method

2

Description

Motor Block

Timepoint

After spinal up to complete motor block, 10, 20, 30, 60, 90, 120 minutes after spinal

Method of measurement

Bromage scale

Secondary outcomes

1

Description

Atropin

Timepoint

During Surgery

Method of measurement

Usage dose (milligram)

2

Description

Ephedrin

Timepoint

During Surgery

Method of measurement

Usage dose (milligram)

3

Description

Nausea and Vomiting

Timepoint

During and After Surgery

Method of measurement

Observation-Yes/No

Intervention groups

1

Description

Group A : 0.1 mg Epinephrine + 25 microgram Fentanyl + 12-15 mg Bupivacaine.(According Methods) Fentanyl: Darou Pakhsh Company Bupivacaine: Aburaihan Company Epinephrine: Darou Pakhsh Company

Category

Treatment - Drugs

2

Description

Group B : 0.3 mg Epinephrine + 25 microgram Fentanyl + 12-15 mg Bupivacaine.(According Methods) Fentanyl: Darou Pakhsh Company Bupivacaine: Aburaihan Company Epinephrine: Darou Pakhsh Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Pejman Pourfakhr

Street address

Sina Hospital, Hasan Abad Sq, Imam Khomeini St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Sina Hospital

Full name of responsible person

Dr. Reza Shariat Moharari

Street address

Sina Hospital, Hasan Abad Sq, Imam Khomeini St.

City

Tehran

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 Sina Hospital

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

Sina Hospital

Full name of responsible person

Negin Saeedi

Position

BS-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