

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of postoperative analgesia and side effects of ropivacaine and bupivacaine by continuous epidural analgesia after lower extremity orthopedic surgery

Protocol summary

Summary

After written informed consent, 120 ASA I and II patients scheduled for lower orthopedic surgery under epidural anesthesia were selected for this study. Inclusion criteria: age between 18-65 years old; ASA I and II and scheduled for lower extremity orthopedic surgery. Exclusion criteria: Opioid addiction or abuse; lower extremity muscle weakness; hypersensitivity to opioids; patient refusal at any time during project and coagulopathy or anticoagulant therapy. Postoperative pain relief was performed by PCA (Patient Controlled Analgesia) as continuous epidural analgesia and 5ml/h infusion rate. The patients were randomly allocated into two groups: 1- (R group) ropivacaine 0.3% plus fentanyl (2 mcg/ml) and 2- (B group) bupivacaine 0.2% plus fentanyl (2 mcg/ml). If the pain score (VAS) was more than 3, fentanyl 1mcg/kg iv was slowly administered. Pain assessed by Visual Analogue Score (0= no pain, 10= the worst imaginable pain) and Verbal Rating Scale (0= no pain, 1= mild, 2= moderate, and 4= severe pain). Motor blockade was assessed by Bromage scale (0= complete lower limb movement, 1= unable to hip flexion, 2= unable to knee flexion, and 3= unable to ankle flexion). Nausea and vomiting assessed as 1) no nausea and vomiting, 2) mild nausea without need to medication, 3) nausea need to medication, 4) unresponsive to single dose of anti-emetic drug. Patient satisfaction evaluated by: 1) excellent, 2) good, 3) fair, and 4) dissatisfied. Also, presence or absence of itching and urinary retention were recorded. All above data were recorded at immediate before pump filling, 6, 12, 24, 36 and 48 hours later. Collected data were analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202277984N4**

Registration date: **2012-05-30, 1391/03/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-30, 1391/03/10

Registrant information

Name

Farnad Imani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences (TUMS)

Expected recruitment start date

2012-02-19, 1390/11/30

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of postoperative analgesia and side effects

of ropivacaine and bupivacaine by continuous epidural analgesia after lower extremity orthopedic surgery

Public title

Comparison of postoperative analgesia and side effects of ropivacaine and bupivacaine by continuous epidural analgesia after lower extremity orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-65 years old; ASA I and II and scheduled for lower extremity orthopedic surgery. Exclusion criteria: Opioid addiction or abuse; lower extremity muscle weakness; hypersensitivity to opioids; patient refusal at any time during project and coagulopathy or anticoagulant therapy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences (TUMS)

Street address

Poursina St, Tehran

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Tehran

Postal code

1445613131

Approval date

2012-02-12, 1390/11/23

Ethics committee reference number

90-03-30-12927-46840

Health conditions studied

1

Description of health condition studied

Analgesia after lower extremity orthopedic surgery

ICD-10 code

M96.6

ICD-10 code description

Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate

Primary outcomes

1

Description

Pain

Timepoint

data were recorded at immediate before pump filling, 6, 12, 24, 36, and 48 hours later

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Motor blockade

Timepoint

data were recorded at immediate before pump filling, 6, 12, 24, 36, and 48 hours later

Method of measurement

Bromage scale

Intervention groups

1

Description

Ropivacaine in case group

Category

Treatment - Drugs

2

Description

Bupivacaine in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Medical Center

Full name of responsible person

Farnad Imani

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Department of Anesthesiology and Pain Medicine,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Deputy, Tehran University of Medical
Sciences (TUMS)

Full name of responsible person

Dr Fotouhi

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Tehran University of Medical Sciences (TUMS), Ghods
St, Keshavarz Blv,

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy, Tehran University of Medical Sciences
(TUMS)

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

Farnad Imani

Position

Chairman , Department of Anesthesiology

Other areas of specialty/work**Street address**

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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