Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Summary

Sixty patients undergoing lower limb orthopedic surgery with torniquet 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

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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 torniquet

Public title
Effects of adding different doses of epinephrine to the fentanyl and bupivacaine solution in spinal anesthesia in lower limb orthopedic surgeries with torniquet
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: candidates of lower limb orthopedic surgeries with torniquet 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 Envelolope

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.
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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
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
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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