Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of 3-in-1 block with bupivacaine 0.25% versus bupivacaine 0.25% plus 8 milligram dexamethaasone in acute pain control of patients undergone hip nailing surgery

Protocol summary

Summary

The purpose of this randomized, double blinded clinical trial is to evaluate the effect of 3-in-1 block with bupivacaine 0.25% versus bupivacaine 0.25% plus 8 milligrams of dexamethasone in acute pain control of the patients undergoing elective hip nailing surgery. So we will randomly divide 44 ASA class I-III patients into two groups and depending on the group the patient will receive 3-in-1 block with bupivacaine 0.25% or bupivacaine 0.25% plus 8 milligrams of dexamethasone at the end of the surgery and we will measure post operative pain score with visual analog scale in certain periods of time during 24 hours post operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201158728N1**
Registration date: **2012-02-25, 1390/12/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-02-25, 1390/12/06

Registrant information

Name

Afshin Amini

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1623 5280

Email address

khalediar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-04-18, 1391/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 3-in-1 block with bupivacaine 0.25% versus bupivacaine 0.25% plus 8 milligram dexamethaasone in acute pain control of patients undergone hip nailing surgery

Public title

The effect of femoral block with bupivacaine in pain control of patients undergone hip nailing surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age: 50-80; ASA Class: I-III; Elective surgery. Exclusion criteria: Patients <50 or >80 years old; Weight >110 or <50; History of substance abuse and addiction; History of allergy to local anesthetics; Peripheral neuropathy; any neurologic deficit; Abnormal coagulation profile; Mental retardation; dementia; Inability to undrestand the pain score system.

Age

From **50 years** old to **80 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Postal code
Approval date
2012-01-05, 1390/10/15
Ethics committee reference number
CT-90-1953

Health conditions studied

1

Description of health condition studied
Intertrochanteric fracture
ICD-10 code
S72.1
ICD-10 code description
Intertrochanteric fracture , Trochanteric fracture

Primary outcomes

1

Description
Pain
Timepoint
Hours of 0, 1/2 , 1, 6, 12, 24
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Failure of block
Timepoint
Hours of 0 and 1/2
Method of measurement
Presense of sense in the territory of 2 blocked nerves

2

Description
Nausea and/or vomiting
Timepoint
Hours of 0, 1/2 and 1
Method of measurement
Physician observation or patient complaint

3

Description
Arrhythmia and/or hypotension
Timepoint
Hours of 0, 1/2 and 1
Method of measurement
Monitoring the patient

4

Description
Hematoma
Timepoint
Hours of 0, 1/2, 1, 6, 12, 24
Method of measurement
Physician observation

Intervention groups

1

Description
For the control group: After approval of ethics committee, written and verbal consent will be obtained from the patients. All patients will be instructed on the 10 point visual analog scale. Anesthetic induction will be achieved with 0.03 mg/kg midazolam, 2 µ/kg fentanyl, 4-6 mg/kg thiopental and 0.5-0.6 mg/kg atracurium. For maintenance we will administer 1- 1.5 % Isoflurane and 50% N2O-50% O2 mixture. Remifentanil will be added (0.1-0.2 µg/kg/min) when there is an increase more than 30% from the baseline mean blood pressure or pulse during the surgery. At the end of surgery reversal will be administered for reversing muscle relaxation and before the patient is awake, with sufficient disinfection of the area, femoral 3-in-1 block will be performed by a physician blinded to study. The femoral nerve will be localized with the help of the peripheral nerve stimulator B|Braun. The presence of continuing contractions in the

quadriceps femoris muscle at a value of 0.5 mA is acceptable. While the needle is held in this position, 40 ml of 0.25% bupivacaine solution will be injected following a negative aspiration. The injection will be carried out within a period of two minutes with distal pressure application to increase the spread of the local anesthetic within the psoas sheath. After that the patient will be transferred to recovery with endotracheal tube and will be extubated in recovery room after awakening. The patients will be monitored for blood pressure, heart rate and O2 saturation for 1 hour and also they will be evaluated for any side effects such as nausea, vomiting, arrhythmia, decreased level of consciousness, hypotension and hematoma in the site of injection. Presence of sensory block in the femoral, obturator and lateral cutaneous nerve dermatomes will be tested with the pin-prick and if there is sense on the territory of 2 nerves the patient will be omitted from the study due to failure of block and another patient will be replaced. Pain score will be measured by visual analog scale (VAS) at the times of 0, 1/2, 1, 6, 12, and 24 (One hour after block is time 0) by a physician blinded to group of the patient. A VAS value of 3 will be accepted as an adequate level of analgesia. During the study if the patient develops VAS ≥ 4, 2 milligrams of IV morphine will be administered slowly every half hour if necessary till it reaches below 4. Finally the patients will be asked to evaluate the general satisfaction of the pain treatment at the end of 24 hours (3=perfect, 2=good, 1=moderate and 0=bad).

Category

Treatment - Drugs

2

Description

For the intervention group: After approval of ethics committee, written and verbal consent will be obtained from the patients. All patients will be instructed on the 10 point visual analog scale. Anesthetic induction will be achieved with 0.03 mg/kg midazolam, 2 µ/kg fentanyl, 4-6 mg/kg thiopental and 0.5-0.6 mg/kg atracurium. For maintenance we will administer 1- 1.5 % Isoflurane and 50% N2O-50% O2 mixture. Remifentanil will be added (0.1-0.2 µg/kg/min) when there is an increase more than 30% from the baseline mean blood pressure or pulse during the surgery. At the end of surgery reversal will be administered for reversing muscle relaxation and before the patient is awake, with sufficient disinfection of the area, femoral 3-in-1 block will be performed by a physician blinded to study. The femoral nerve will be localized with the help of the peripheral nerve stimulator B|Braun. The presence of continuing contractions in the quadriceps femoris muscle at a value of 0.5 mA is acceptable. While the needle is held in this position, 40 ml of 0.25% bupivacaine plus 8 milligrams of dexamethasone solution will be injected following a negative aspiration. The injection will be carried out within a period of two minutes with distal pressure application to increase the spread of the local anesthetic within the psoas sheath. After that the patient will be transferred to recovery with endotracheal tube and will be extubated in recovery room after awakening. The patients will be monitored for blood pressure, heart rate and O2 saturation for 1 hour and also they will be evaluated for any side effects such as nausea, vomiting, arrhythmia, decreased level of consciousness, hypotension and hematoma in the site of injection. Presence of sensory block in the femoral, obturator and lateral cutaneous nerve dermatomes will be tested with the pin-prick and if there is sense on the territory of 2 nerves the patient will be omitted from the study due to failure of block and another patient will be replaced. Pain score will be measured by visual analog scale (VAS) at the times of 0, 1/2, 1, 6, 12, and 24 (One hour after block is time 0) by a physician blinded to group of the patient. A VAS value of 3 will be accepted as an adequate level of analgesia. During the study if the patient develops VAS ≥ 4, 2 milligrams of IV morphine will be administered slowly every half hour if necessary till it reaches below 4. Finally the patients will be asked to evaluate the general satisfaction of the pain treatment at the end of 24 hours (3=perfect, 2=good, 1=moderate and 0=bad).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Amin Reza Khaledi - Resident of anesthesiology and critical care

Street address

Chamran Boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Afshin Amini M.D

Street address

Central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Amin Reza Khaledi M.D
Position
Resident of anesthesiology and critical care
Other areas of specialty/work
Street address
Department of anesthesiology, Faghihi Hospital
City
Shiraz
Postal code
Phone
+98 71 1623 5280
Fax
Email
khalediar@sums.ac.ir;khaledi_amin@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Afshin Amini M.D
Position
Assistant Professor of anesthesiology
Other areas of specialty/work
Street address
Asateed-e Daneshghah Building, East Ghoddoosi boulevard
City
Shiraz
Postal code
Phone
+98 71 1233 1549
Fax
Email
aamini@sums.ac.ir;afshinaminie@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Amin Reza Khaledi M.D
Position
Resident of anesthesiology and critical care
Other areas of specialty/work
Street address
Department of anesthesiology, Faghihi Hospital
City
Shiraz
Postal code
Phone
+98 71 1623 5280
Fax
Email
khalediar@sums.ac.ir;khaledi_amin@yahoo.com
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