Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of adding magnesium to bupivacaine for femoral nerve block on postoperative pain in patients undergoing knee and femoral orthopedic operations

Protocol summary

Summary

(1) Objectives: Determining efficacy of adding magnesium sulfate to bupivacaine with bupivacaine alone in femoral block for postoperative analgesia in femoral and knee operations. (2) Design: Sixty patients who undergoe knee and femur surgery select and divide in two groups with 30 patients in a double blind study for random clinical test.(3) Setting and conduct: After informed consent block perform with sonnoguidance and nerve stimulator for confirming the nerve location and patients undergoe femur and knee surgery with spinal anesthesia divide in two groups with 30 membrs. In first group use 20cc bupivacaine 0.2%and in second group 19.6cc bupivacaine 0.2%with 0.4cc magnesium sulfate (200mg). The person who perform the block dosn,t know anything about drug nature. Aaccording to the qustionnare in all patients major variables included VAS /sedation RAMSY score /bromage score before and after block in times T1(before block)-T2(just after block)-3-6-12after that and the amount of additional analgesic evaluate. The quetionnare will complete with person who dosn,t know anything about the nature of drugs. (4) Inclusion criteria: Patients' consent؛ No usage of anti- coagulant drugs؛ No infection at the site of injection؛ Age between 18 and 65 years old ؛ASA1&2 Exclusion criteria: Patient refusal(no consent of the patients) ؛Surgery on PCL؛ Any complication due to injection or drugs, Calcium channel blocker usage, History of advanced renal disease؛ Allergy to drugs and Central or peripheral neurologic disorders.(5) Intervention: Before block in all of the patients major variables such as VAS/RAMSY SCORE/BROMAGE SCORE and after block the listed variable with the amount of probable additional analgesic (20mg pethedin)and patient satisfication in times T1 before block-T2 after block-3-6-12 hours after that will control. Person who complete the questionnaire dosn,t know anythine about nature of injected drugs. (6) Main outcome measures variables: Major variables are VAS and RAMSY sedation score and BROMAGE score and after the block this criteria with the amount of probable needed analgesic (20 mg pethedine IM)and patient satisfication evaluate. Statistical analysis perform with SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410137984N19**
Registration date: **2014-12-26, 1393/10/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-26, 1393/10/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran university of medical sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding magnesium to bupivacaine for femoral nerve block on postoperative pain in patients undergoing knee and femoral orthopedic operations

Public title

The effect of adding magnesium to bupivacaine for femoral nerve block on postoperative pain in patients undergoing knee and femoral orthopedic operations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients' consent؛ No usage of anti-coagulant drugs؛ No infection at the site of injection؛ Age between 18 and 65 years old؛ ASA1&2 Exclusion criteria: Patient refusal(no consent of the patients)؛ Surgery on PCL؛ Any complication due to injection or drugs, Calcium channel blocker usage, History of advanced renal disease؛ Allergy to drugs and Central or peripheral neurologic disorders.

Age

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

Gender

Both

Phase

2-3

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran university of medical sciences

Street address

Ethic committee ,Iran university of medical sciences, Hemmat Highway

City

Tehran

Postal code

Approval date

2014-08-24, 1393/06/02

Ethics committee reference number

93-02-30-24667-103610

Health conditions studied

1

Description of health condition studied

Postoperative Analgesia

ICD-10 code

R52

ICD-10 code description

Acute pain

2

Description of health condition studied

Postoperative Analgesia

ICD-10 code

T84.8

ICD-10 code description

Pain due to orthopedic internal implantation, fixation and other procedure

Primary outcomes

1

Description

pain score

Timepoint

before block-just after block-3-6-12 hours after block

Method of measurement

visual analog scale

Secondary outcomes

1

Description

Sedation

Timepoint

Just after block and 3-6-12 hours after block

Method of measurement

Sedation score

2

Description

Satisfication

Timepoint

Just after block and 3-6-12 houres after block

Method of measurement

Questionnare

3

Description
Additional requirement for opioid analgesics
Timepoint
Just after block and 3-6-12 hours after block
Method of measurement
Total dosage of injected additional analgesic in miligram

Intervention groups

1

Description
After the written informed consent from the patients in the study the femoral block perform with guide of sonography and nerve stimulator on the lateral side of femoral artery below the inguinal ligament for confirming the nerve location. In first group30 patient with femur or knee surgery by spinal anesthesia 19.6cc bupivacaine 0.2% with 0.4cc magnesium sulfate 50%(200 mg)perform injection. According to the questionnaire in all of patients the major variables such as VAS ,sedation score,bromage score before block and just after block and in times 3-6-12 after that the same criteria with the consumption of any other analgesic and patient satisfication will evaluate and record. For patients in this study questionnaire fille out by someone who does not know the nature of the injected drugs.
Category
Treatment - Drugs

2

Description
After the written informed consent from the patients in the study the femoral block perform with guide of sonography and nerve stimulator on the lateral side of femoral artery below the inguinal ligament for confirming the nerve location. In second group30 patient with femur or knee surgery by spinal anesthesia with 20cc bupivacaine 0.2% perform injection. According to the questionnaire in all of patients the major variables such as VAS ,sedation score,bromage score before block and just after block and in times 3-6-12 after that the same criteria with the consumption of any other analgesic and patient satisfication will evaluate and record. For patients in this study questionnaire fille out by someone who does not know the nature of the injected drugs.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul-Akram Medical Centre
Full name of responsible person
Dr. Farnad Imani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Dr. Ali Javad Mousavi
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Vice chancellor for research, Iran University of Medical Sciences, Hemmat highway,Tehra,Iran
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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, Iran 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
Iran University of Medical Sciences
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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