# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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**
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**City**
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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
**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, 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

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## Person responsible for updating data

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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*