

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of analgesic effect of intra articular ((bupivacaine)) with ((magnesium sulphate and bupivacaine)) following knee arthroscopy under spinal anesthesia.

Protocol summary

Summary

This research is conducted for comparison of analgesic effect of intra articular ((bupivacaine)) with ((magnesium sulphate and bupivacaine)) following knee arthroscopy under spinal anesthesia. Inclusion criteria are: patients who are candidate for arthroscopic knee surgery having ASA class 1, 2 and their age range between 18 to 60 years. Exclusion criteria are: patients with contraindication for spinal anesthesia or refuse spinal anesthesia; patient with chronic pain or allergy to local anesthetics and patients with history of chronic analgesic use (nonsteroidal anti-inflammatory drugs, opioids, or paracetamol). Forty five patients undergoing arthroscopic knee surgery under spinal anesthesia with 2 ml bupivacaine 0.5% were randomized blindly into one of three parallel groups. The saline placebo group (group A) received 10 mL of isotonic saline, The bupivacaine group (group B) received 0.20% (10 mL) bupivacaine, whereas the magnesium with bupivacaine group (group MB) receive bupivacaine 0.20% and 1 g of magnesium sulfate in 10 mL at the end of surgery and before release of the tourniquet. The postoperative pain will be assessed using NRS recorded after surgery at 4, 6, 8, 12, and 24 hours. Patients will be evaluated at rest.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106026687N1**

Registration date: **2011-09-21, 1390/06/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-21, 1390/06/30

Registrant information

Name

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Name of organization / entity

Ahwaz Jondishapoor University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jondishapoor University of Medical Sciences

Expected recruitment start date

2010-11-28, 1389/09/07

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of intra articular ((bupivacaine)) with ((magnesium sulphate and bupivacaine)) following knee arthroscopy under spinal anesthesia.

Public title

Comparison of analgesic effect of intra articular ((bupivacaine)) with ((magnesium sulphate and bupivacaine)) following knee arthroscopy under spinal anesthesia.

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: patients' age between 18 to 60 years and patients having ASA class 1 or 2 Exclusion criteria: having contraindication for spinal anesthesia or refuse spinal anesthesia; patients with chronic pain or allergy to local anesthetics and patients with history of chronic analgesic use (nonsteroidal anti-inflammatory drugs, opioids, or paracetamol)

Age
 From **18 years** old to **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **45**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapoor University of Medical Sciences

Street address

Shahr-e Daneshgah

City

Ahvaz

Postal code

6135715794

Approval date

2010-11-27, 1389/09/06

Ethics committee reference number

eth019

Health conditions studied

1

Description of health condition studied

Pain relief after knee arthroscopy surgery

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Pain

Timepoint

4, 6, 8, 12 and 24 hours after

Method of measurement

Numeric rating scale

Secondary outcomes

1

Description

Pethidine consumption

Timepoint

4, 6, 8, 12 and 24 hours post operation

Method of measurement

Medical records

Intervention groups

1

Description

The first intervention group receives 0.20% (10 mL) bupivacaine intra articularly

Category

Prevention

2

Description

The second intervention group receives bupivacaine 0.20% and 1 g of magnesium sulfate in 10 ml saline solution intra articularly

Category

Prevention

3

Description

The third intervention group receives 10 mL of isotonic saline intra articularly

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital, Ahvaz Jondishapoor University of Medical Sciences

Full name of responsible person

Dr.Mohamad Reza Pipelzadeh

Street address

Ahwaz, Imam Khomeini hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jondishapoor University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhy

Street address

University city

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jondishapoor 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

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Dr. Mohamad Reza Pipelzadeh

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Lecturer

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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