Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of intra-articular injection of Bupivacaine and Morphine versus Bupivacaine and Methyl prednisolone on postoperative pain after knee surgery

Protocol summary

Summary

Objectives: The purpose of this study is to compare the effect of intra-articular injection of Bupivacaine and Morphine versus Bupivacaine and Methyl prednisolone on postoperative pain in patients who are candidate for repairing anterior cruciate ligament through an arthroscopic knee surgery. Design: Study carry out in a single blind manner, one centric clinical trial and by simple randomized method (Sealed Envelope and the selection of colorful cards) on 105 patients with 20 to 80 year's old, candidate for arthroscopic knee surgery in Rajaii hospital of Qazvin. Setting and conduct: Patients are randomly dividing into three groups (n= 35). In all patients Induction of anesthesia and route of surgery are the same Intervention: patients receive intra-articular injection of 8 ml bupivacaine 0.5 % with 5 mg morphine in group 1, 8 ml bupivacaine 0.5 % with 40 mg methylprednisolone in group 2, 8 cc bupivacaine 0.5 % with 1 ml distilled water in group 3 At the end of the surgery . Main outcome measures: Pain is assessed through visual analog scale (VAS) at 1, 2, 6, 12, 18 and 24 hours after the surgery. In addition, the amount of opioid consumption, and side effects of used drugs will evaluated during 24 hours after surgery and compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083125676N5**
Registration date: **2017-02-22, 1395/12/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-22, 1395/12/04

Registrant information

Name

Hamid Kayalha

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intra-articular injection of Bupivacaine and Morphine versus Bupivacaine and Methyl prednisolone on postoperative pain after knee surgery

Public title

Comparison the effect of intra-articular injection of

Bupivacaine and Morphine versus Bupivacaine and Methyl prednisolone on postoperative pain after knee surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients 20–80 years old; with American Society of Anesthesiologists (ASA) physical status I or II; scheduled for arthroscopic knee surgery. Exclusion criteria: Patient with neuropathic pain; neurologic deficit in respective organ; surgical history on respective knee; any allergy to used drug; BMI>40; Presence of underlying diseases (cardiac, renal, arthritis & diabetes); chronic pain; coagulopathy; opium addiction.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization method (Sealed envelope and the selection of colorful cards)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Medical Sciences

Street address

Shahid Bahonar Blvd, Qazvin.

City

Qazvin

Postal code

3419759811

Approval date

2016-10-29, 1395/08/08

Ethics committee reference number

IR.QUMS.REC.1395.120

Health conditions studied

1

Description of health condition studied

pain in knee

ICD-10 code

M79.6

ICD-10 code description

Pain in limb

Primary outcomes

1

Description

postoperative pain

Timepoint

1, 2, 6, 12, 18 and 24 hours after surgery

Method of measurement

Score of pain in Visual analog scale (VAS)

2

Description

Opioid consumption

Timepoint

During 24 hours after operation

Method of measurement

Mg of Pethidine

Secondary outcomes

1

Description

Drug side effects

Timepoint

During 24 hrs after the surgery

Method of measurement

Asking the patient

Intervention groups

1

Description

At the end of the surgery in group 1:intra-articular injection of 8 ml bupivacaine 0.5 % with 5 mg morphine will be done

Category

Prevention

2

Description

At the end of the surgery in group 2: intra-articular injection of 8ml bupivacaine 0.5 % with 40 mg methylprednisolone will be done

Category

Prevention

3

Description
At the end of the surgery in group 3: intra-articular injection of 8 ml bupivacaine 0.5 % with 1 ml distilled water will be done
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaee Hospital
Full name of responsible person
Dr Hamid Kayalha
Street address
Rajaee Hospital, Padegan Avenu, Qzvin.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Qazvin University of Medical Sciences
Full name of responsible person
Dr. Taghi Naserpour
Street address
Shahid Bahonar Blvd, Qazvin
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Qazvin
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 Qazvin 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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Fax
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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