Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Addition of Clonidine to Bupivacaine in Spinal Anesthesia on Analgesia and Hemodynamic after Cruciate Ligament Repair: A Randomized Double Blinded Clinical Trial

Protocol summary

Summary

This study sought to assess the effect of addition of clonidine to bupivacaine in spinal anesthesia on analgesia after cruciate ligament repair. Fifty patients undergoing ACL reconstruction surgery divided into two groups. An anesthesiologist prepared drugs and another anesthesiologist injected drugs for patients. The first group received 0.5% bupivacaine with a total dose of 15 mg plus 0.5 ml saline solution and group 2 received 15 mg 0.5% bupivacaine plus 75 µg clonidine with a total volume of 0.5 ml intrathecally. Patients received 1-2 mg midazolam for sedation prior to surgery and 5ml/kg saline solution during 15-20 min. During the operation, oxygen supplementation was carried out at a rate of 6 L/min. Spinal anesthesia was induced using a #26 needle inserted through L3-L4 or L4-L5 with midline method. During the operation, 1 mg midazolam was administered if sedation was needed. Patient's blood pressure, Ramsay score, VAS, SpO2 and pulse rate were measured and recorded every 15 min. Time to request analgesics and the VAS score at the time of request were also recorded. These data were compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062117413N5**
Registration date: **2014-06-29, 1393/04/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-29, 1393/04/08

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences Deputy of Research

Expected recruitment start date

2013-07-11, 1392/04/20

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Addition of Clonidine to Bupivacaine in Spinal Anesthesia on Analgesia and Hemodynamic after Cruciate Ligament Repair: A Randomized Double Blinded Clinical Trial

Public title

Effect of Addition of Clonidine to Bupivacaine in Spinal Anesthesia on Analgesia after Cruciate Ligament Repair

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients candidate ACL reconstruction surgery under spinal anesthesia at Baqiyatallah Hospital; Age over 18. Exclusion criteria: history of chronic pain; multiple trauma; long-term consumption of opioids and analgesics; history of alcohol consumption; absolute or partial contraindication of spinal injections; allergy to clonidine and bupivacaine.

Age
From **18 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

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
Baqiyatallah University of Medical Sciences Ethics Committee

Street address
Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City
Tehran

Postal code

Approval date
2013-05-06, 1392/02/16

Ethics committee reference number
30-22

Health conditions studied

1

Description of health condition studied
Sprain and strain involving (anterior)(posterior) cruciate ligament of knee

ICD-10 code
S83.5

ICD-10 code description
injury of cruciate ligament of knee

Primary outcomes

1

Description
Two Sensory Dermatome Regression Time

Timepoint
After operation

Method of measurement
Minute

2

Description
Motor Regression time

Timepoint
After operation

Method of measurement
Minute

3

Description
Post operative pain severity

Timepoint
at the time of needing analgesia

Method of measurement
visual analogue score (0-10)

4

Description
Time of needing analgesia

Timepoint
After operation

Method of measurement
Minute

Secondary outcomes

1

Description
voiding time

Timepoint
After operation

Method of measurement
Minute

2

Description
Blood pressure

Timepoint
After operation

Method of measurement
mmHg

Intervention groups

1

Description
Second group received 15 mg 0.5% bupivacaine plus 75 µg clonidine with a total volume of 0.5 ml intrathecally.
Category
Treatment - Drugs

2

Description
The first group received 0.5% bupivacaine with a total dose of 15 mg plus 0.5 ml saline solution intrathecally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Marzieh Lak
Street address
Baqiyatallah Hospital, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences, Deputy of Research
Full name of responsible person
Marzieh Lak
Street address
Baqiyatallah Hospital, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.
City
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Baqiyatallah University of Medical Sciences, Deputy of Research
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
Students' Research Committee (SRC), Baqiyatallah University of Medical Sciences, Tehran, IR Iran
Full name of responsible person
Hamidreza Karimi Sari
Position
General Practitioner
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Marzieh Lak
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Associate Professor
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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