

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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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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.

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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

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Name of organization / entity

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University of Medical Sciences, Tehran, Iran

Full name of responsible person

Marzieh Lak

Position

Associate Professor

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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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