

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of adding clonidine to bupivacaine in supraclavicular block with catheter insertion for upper extremity surgery

Protocol summary

Summary

Goals: Evaluation of sensory and motor blockade and side effects of adding clonidine 75 mcg to bupivacaine in supraclavicular brachial plexus blockade with catheter insertion for upper extremity procedures. Methods: In this randomized, double-blind, controlled trial, sixty patients, aged 20–60 years, with ASA (American Society of Anesthesiologists) status classification I or II who were candidate for upper extremity orthopedic surgery under supraclavicular brachial plexus blockade were allocated in two groups (30 in each group). The supraclavicular blockade was performed by peripheral nerve stimulator and anesthetic solutions were injected after desirable muscular responses. Control group (B) received 0.5% bupivacaine 25 ml, and study group (BC) received 0.5% bupivacaine 25 ml contained 75 mcg clonidine. After that, supraclavicular catheter was indwelt for additional injections. For additional intraoperative analgesia, 5 ml of bupivacaine 0.5% was administrated through catheter, along with IV sufentanil and midazolam. Onset of complete sensory and motor blockade, intraoperative drug administrated (bupivacaine, sufentanil and midazolam) complications, duration of postoperative analgesia and motor blockade, time to first postoperative analgesic request, and demographic data were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805312366N1**

Registration date: **2010-02-20, 1388/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-20, 1388/12/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences (IUMS)

Expected recruitment start date

2003-12-22, 1382/10/01

Expected recruitment end date

2004-12-21, 1383/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of adding clonidine to bupivacaine in supraclavicular block with catheter insertion for upper extremity surgery

Public title

Evaluation of adding clonidine to local anesthetic in regional anesthesia for upper extremity surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 20–60 years (ASA physical status I or II) of both sex, who were candidate

for upper extremity (hand, forearm, elbow or arm) surgery, referred to Rasool-Akram hospital. Exclusion criteria: severe uncontrolled underlying diseases (coagulopathy, seizure, cardiac, ...), history of cigarette, opioid, or alcohol abuser, allergy to local anesthetic or clonidine , patient refusal

Age

From **20 years** old to **60 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

Iran University of Medical Sciences

Street address

Crossroads of Hemmat & Chamran Expressways

City

Tehran

Postal code

14496

Approval date

2009-05-04, 1388/02/14

Ethics committee reference number

161

Health conditions studied

1

Description of health condition studied

Fracture of upper limb

ICD-10 code

T10

ICD-10 code description

Fracture of upper limb

2

Description of health condition studied

Local anaesthetics

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

sensory and motor blockade in upper extremity

Timepoint

from start of injection to one hour after surgery

Method of measurement

physical exam of sensation and movement in the upper limb

Secondary outcomes

1

Description

complications

Timepoint

from start of injection to one hour after surgery

Method of measurement

patient evaluation and observation

Intervention groups

1

Description

Intervention group: adding clonidine 75 mcg to bupivacaine 0.5% in supraclavicular blockade

Category

Treatment - Drugs

2

Description

Control group: administration of 25 ml bupivacaine 0.5% for supraclavicular blockade

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-Akram Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences (IUMS)

Full name of responsible person

Akbar Sharafi M.D. Vice chancellor for research

Street address

Crossroads of Hemmat & Chamran Expressways

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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

Iran University of Medical Sciences (IUMS)

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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Full name of responsible person

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Position

Chairman, Department of Anesthesiology

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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