Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 administraded (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 surgry

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 surgry

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

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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