Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Effect of Ultra Low Dose Naloxane and/or fentanyl on the onset time and duration of Supraclavicular Block using Bupivacaine 0.5%

Protocol summary

Summary

Sixty-eight patients scheduled for elective forearm and arm surgery under ultrasound guided supraclavicular brachial plexus block are randomly allocated to receive 30 mL bupivacaine 0.5% with 3 mL of isotonic saline chloride (C Group, n = 15), 30 mL bupivacaine 0.5% with 2 mL (100 µg) of fentanyl and 1 mL of isotonic saline chloride(F Group, n = 15), 30 mL bupivacaine 0.5%with 2 mL isotonic saline chloride and 100ng (1 mL) naloxone (N Group, n = 15), or 30 mL bupivacaine 0.5%with 2 mL(100 µg) of fentanyl and 100 ng (1 mL) naloxone (N + F Group, n = 15). The onset and duration of sensory and motor blockade are recorded in the 4 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209175140N6**
Registration date: **2012-09-25, 1391/07/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-09-25, 1391/07/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-10-10, 1391/07/19

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ultra Low Dose Naloxane and/or fentanyl on the onset time and duration of Supraclavicular Block using Bupivacaine 0.5%

Public title

Effect of Naloxane and/or Opioids on Supraclavicular Block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with American Society of Anesthesiologists physical status class I and II. Exclusion Criteria: Hepatic or Renal failure; Heart diseases; history of drug allergy; substance abuse (including opioids and benzodiazepines); morbid obesity; history of postoperative nausea and vomiting (PONV); history of motion sickness; smokers.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

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
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Faculty of Medicine, Tehran University of Medical Sciences and Health Care

Street address
Faculty of Medicine, Tehran University of Medical Sciences and Health Care

City
Tehran

Postal code

Approval date
2011-08-20, 1390/05/29

Ethics committee reference number
90/74982

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
R52.0

ICD-10 code description
acute pain

Primary outcomes

1

Description
Sensory block Onset time and duration

Timepoint
Every 5 minutes from supraclavicular block

Method of measurement
measurement of time

2

Description
Motor block onset and duration time

Timepoint
Time from supraclavicular block, every 5 minutes

Method of measurement
measurement of time

Secondary outcomes

1

Description
Pruritus

Timepoint
Time from supraclavicular block, every 5 minutes

Method of measurement
measurement of time

Intervention groups

1

Description
30 mL bupivacaine 0.5% with 3 mL of isotonic saline chloride

Category
Treatment - Drugs

2

Description
30 mL bupivacaine 0.5% with 2 mL (100 µg) of fentanyl and 1 mL of isotonic saline chloride

Category
Treatment - Drugs

3

Description
30 mL bupivacaine 0.5%with 2 mL isotonic saline chloride and 100ng (1 mL) naloxone

Category
Treatment - Drugs

4

Description
30 mL bupivacaine 0.5%with 2 mL(100 µg) of fentanyl and 100 ng (1 mL) naloxone

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Shariati Hospital

Full name of responsible person

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Shahin Akhoondzadeh
Street address
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City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Contact
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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