

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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Name of organization / entity

Tehran University of Medical Sciences

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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

Tehran University of Medical Sciences and Health Services

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

Name of organization / entity

Dr. Shariati Hospital

Full name of responsible person

Dr. Ali Movafegh

Position

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Full name of responsible person

Omid Azimaraghi

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Other areas of specialty/work

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Fax

Email

Web page address

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