# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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**

**Name**
Omid Azimaraghi
**Name of organization / entity**
Tehran University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 2206 6194
**Email address**
cazimaraghi@tums.ac.ir

**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**
Professor
**Other areas of specialty/work**
**Street address**
Kargar ave, Shariati Hospital
**City**
Tehran
**Postal code**
**Phone**
+98 21 8809 1214
**Fax**
**Email**
movafegh@tums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Dr. Shariati Hospital
**Full name of responsible person**
Dr.Ali Movafegh
**Position**
Professor
**Other areas of specialty/work**
**Street address**
North Kargar Ave,Dr. Shariati Hospital
**City**
Tehran
**Postal code**
**Phone**
+98 21 8801 2397
**Fax**
**Email**
movafegh@tums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
**Full name of responsible person**
Omid Azimaraghi
**Position**
**Other areas of specialty/work**
**Street address**
**City**
**Postal code**
**Phone**
**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*