

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of intravenous administration of Dexmedetomidine on the duration of ultrasound-guided supraclavicular brachial plexus block in comparison with Propofol, in patients undergoing upper extremity surgery in Shariati hospital

#### Protocol summary

##### Summary

Considering the advantages of using Brachial plexus nerve block to perform upper limb surgery and considering the importance of the type of drug used for intraoperative placement during blocking and increasing the duration of post-block analgesia, this study aimed to compare the effect of venous sedation with Dexmedetomidine and Propofol on the duration of Brachial plexus nerve block (supraclavicular technique) under ultrasound guidance in patients undergoing surgical procedure for upper extremity of Shariati Hospital. In this randomized, double blind clinical trial, 88 patients aged 20-50 years undergoing elective orthopedic surgery with ASA III, II, I, BMI below 35 and without a history of drug allergy, after receiving written consent, were divided into two groups of 44, and The start time of the sensory block, motion, and duration of the sensory block are compared to them. A group of supraclavicular injection of 25 ml of bupivacaine solution 0.5% and intravenous infusion of 0.5 mcg / kg / min of dexmedetomidine, and the other group administered supraclavicular injection of 25 ml of bupivacaine 0.5% and intravenous infusion 50mcg / kg / min of propofol. The patient and anesthetist are not informed of the dual bundle form. Then, the sensory and motor blocks are controlled at intervals of 5-10-15-30 minutes after injection and then every 10 minutes after surgery. The level of the sensory block of the nerve is measured by the pinprick test and the patient's question with the analogue speech scale (from 100% normal to 0% completely numb) and the motor block rate is graded from 0 to 5 by the Lovett-rating-scale. The time of onset of the effect of the block of sensory and motor activity as the time between the completion of the last injection and the completion of the sensory and motor paralysis, the duration of the effect of the sensory block in the time

between the completion of the sensory paralysis and the first postoperative pain, the duration of the motor block as the time between the completion of motion palsy and Movement power return is defined as normal. A quantitative study of opioid use is performed by the PCA in a recovery room that contains 30mg of morphine sulfate in 30ml of normal saline. Every time the patient has pain, he injects 1mg of morphine and locks for 15 minutes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017051734005N1**

Registration date: **2017-07-17, 1396/04/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-17, 1396/04/26

##### Registrant information

##### Name

Fatemeh Elmi

##### Name of organization / entity

Medicine Faculty, Tehran university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2221 9958

##### Email address

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##### Recruitment status

**Recruitment complete**

## Funding source

Tehran University of Medical Science

## Expected recruitment start date

2017-06-22, 1396/04/01

## Expected recruitment end date

2018-03-06, 1396/12/15

## Actual recruitment start date

empty

## Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of intravenous administration of Dexmedethomidine on the duration of ultrasound-guided supraclavicular brachial plexus block in comparison with Propofol, in patients undergoing upper extremity surgery in Shariati hospital

## Public title

The effect of intravenous administration of Dexmedethomidine on the duration of ultrasound-guided supraclavicular brachial plexus block in comparison with Propofol, in patients undergoing upper extremity surgery in Shariati hospital

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: age between 20-50 years old; ASA class III, II, I; BMI less than 35; no history of drug allergy; satisfaction of the patient and filling out the consent form. Exclusion criteria: failure to perform supraclavicular block; duration of surgery for more than 180 minutes; cancellation of operation; occurrence of surgical complication during surgery; the need for general anesthesia.

## Age

From **20 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **88**

## 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

Research Ethics Committee of the Medical Faculty of Tehran University of Medical Sciences

##### Street address

Professional Doctoral Theses Unite, Ground Floor, Education Building, Faculty of Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2017-05-01, 1396/02/11

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2175

## Health conditions studied

### 1

#### Description of health condition studied

Local anaesthetics

#### ICD-10 code

T41.3, Y48

#### ICD-10 code description

Local anaesthetics

## Primary outcomes

### 1

#### Description

sensory block onset

#### Timepoint

sensory block will be checked continuously after completion of injection until complete sensory and motor block.

#### Method of measurement

pinprick test and a verbal rating scale from 100% (normal sensation) to 0 (no sensation).

### 2

#### Description

sensory block duration

#### Timepoint

after complete sensory block and every 15 minutes following the end of operation.

#### Method of measurement

pinprick test and a verbal rating scale from 100% (normal sensation) to 0 (no sensation).

### 3

**Description**

motor block onset

**Timepoint**

motor block will be checked continuously after completion of injection until complete motor block.

**Method of measurement**

Lovett rating scale

### 4

**Description**

motor block duration

**Timepoint**

after complete motor block and every 15 minutes following the end of operation

**Method of measurement**

the Lovett rating scale

## Secondary outcomes

### 1

**Description**

Systolic blood pressure

**Timepoint**

continuously monitoring while the surgery is performing

**Method of measurement**

manometer

### 2

**Description**

Diastolic blood pressure

**Timepoint**

continuously monitoring while the surgery is performing

**Method of measurement**

manometer

### 3

**Description**

Heart rate

**Timepoint**

continuously monitoring while the surgery is performing

**Method of measurement**

Monitoring

### 4

**Description**

Respiratory depression

**Timepoint**

continuously monitoring while the surgery is performing

**Method of measurement**

O2 saturation & Respiratory Rate

### 5

**Description**

Drug consumption in the 24 hours after surgery

**Timepoint**

patient need

**Method of measurement**

Medical records

## Intervention groups

### 1

**Description**

groupB: supraclavicular injection of 25 ml of bupivacaine 0.5% and of propofol 50 mcg / kg / min intravenously.

**Category**

Treatment - Drugs

### 2

**Description**

groupA: supraclavicular injection of 25 ml of bupivacaine and 0.5 mg / kg / min of dexamethmonide intravenously

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Dr. Shariati Hospital

**Full name of responsible person**

Dr. Fatemeh Elmi

**Street address**

Shariati hospital, Jalal-e-Al-e-Ahmad high way, district 6, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tehran University Of Medical Sciences Vice Chancellor Of Research

**Full name of responsible person**

Dr Shahin Akhond Zade Basti

**Street address**

Room 206, First Floor, Building 1, Medicine Faculty, Tehran university of medical science

**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 Vice Chancellor Of Research

**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**

Shariati Hospital, Anesthesiology Department

**Full name of responsible person**

Dr. Fatemeh Elmi

**Position**

Medical Student

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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Jalal-Ae-Al-e-Ahmad High Way, District 6, Tehran, Iran

**City****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*