

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Studying the effect of intravenous Propofol used with two different volumes of local anesthetic(Bupivacaine) on sensory and motor blockade in patients undergoing upper limb surgery by sonographic supraclavicular brachial plexus block approach

#### Protocol summary

2017-02-14, 1395/11/26

##### Summary

This study is performed as a controlled randomized clinical trial in order to sedate with a better quality by lower volumes of local anesthetic(Bupivacaine) in patients undergoing upper limb surgery by sonographic supraclavicular brachial plexus blockade. Inclusion and exclusion criteria are applied. Inclusion Criteria are: ages between 20 and 50; ASA classes: I,II,III; BMI under 35; absence of the history of drug induced hypersensitivity; taking of informed consent. Exclusion Criteria are: failure of supraclavicular blockade; need to general anesthesia. Supraclavicular blockade is performed by sonographic guidance after taking informed consent from the patients and randomized division of the patients into 3 different groups based on the use of Propofol or placebo with different volumes of local anesthetic(Bupivacaine). Demographic information and pain score is obtained by interviewing the patients. The onset and duration of sensory and motor blockage is determined by Pinprick Test and Lovett Rating Scale. Hemodynamic information is obtained by monitoring the patients by digital equipments. The onset and duration of sensory and motor blockage is compared in these 3 groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017021430855N1**  
Registration date: **2017-02-14, 1395/11/26**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Mehrdad Sadri

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3724 9292

###### Email address

m-sadri@student.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences, The Vice-Chancellery for Research

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-07-23, 1396/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Studying the effect of intravenous Propofol used with two different volumes of local anesthetic(Bupivacaine) on sensory and motor blockade in patients undergoing upper limb surgery by sonographic supraclavicular brachial plexus block approach

##### Public title

The Effect of Intravenous Propofol on Local Anesthesia

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: Ages between 20 and 50; ASA classes: I,II,III; BMI under 35; Absence of the history of drug induced hypersensitivity; Taking of informed consent

Exclusion Criteria: Failure of supraclavicular blockade; Need to 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: **90**

## 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

Research Ethics Committee of Tehran University of Medical Sciences, School of Medicine

##### Street address

Plate 23, 16th of Azar St, Keshavarz Blvd

##### City

Tehran

##### Postal code

#### Approval date

2016-11-22, 1395/09/02

#### Ethics committee reference number

medicine2IR.TUMS.MEDICINE.REC.1395.1082

## Health conditions studied

### 1

#### Description of health condition studied

Supraclavicular Blochade of the Brachial Plexus

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Duration of Motor Blockage

#### Timepoint

During and after the intervention

#### Method of measurement

Physical examination by the physician

### 2

#### Description

Duration of Sensory Blockage

#### Timepoint

During and after the intervention

#### Method of measurement

Physical examination by the physician

### 3

#### Description

Onset of the Motor Blockage

#### Timepoint

During the intervention

#### Method of measurement

Physical examination by the physician

### 4

#### Description

Onset of the Sensory Blockage

#### Timepoint

During the intervention

#### Method of measurement

Physical examination by the physician

## Secondary outcomes

### 1

#### Description

Patient's feeling of pain

#### Timepoint

After the intervention in the same admission

#### Method of measurement

Visual Analogue Scale (VAS)

### 2

#### Description

The measure of motor blockade

#### Timepoint

During and after the intervention

#### Method of measurement

Lovett Rating Scale

### 3

#### Description

The time of the first opioid request by the patient

#### Timepoint

After the intervention in the same admission  
**Method of measurement**  
By using PCA(Patient Controlled Anaesthesia)

#### 4

**Description**  
Administered opioid dosage in 24 hours  
**Timepoint**  
After the intervention in the same admission  
**Method of measurement**  
Patient Medical Document

#### 5

**Description**  
Duration of the surgery  
**Timepoint**  
During the intervention  
**Method of measurement**  
Patient Medical Document

#### 6

**Description**  
Nausea and vomiting after the surgery  
**Timepoint**  
After the intervention in the same admission  
**Method of measurement**  
Asking the patient

#### 7

**Description**  
Mean arterial blood pressure 1 minute after the blockade  
**Timepoint**  
1 minute after the blockade  
**Method of measurement**  
Non-invasive automatic manometer

#### 8

**Description**  
Mean arterial blood pressure 3 minutes after the blockade  
**Timepoint**  
3 minutes after the blockade  
**Method of measurement**  
Non-invasive automatic manometer

#### 9

**Description**  
Mean arterial blood pressure 5 minutes after the blockade  
**Timepoint**  
5 minutes after the blockade  
**Method of measurement**  
Non-invasive automatic manometer

#### 10

**Description**  
Mean arterial blood pressure 1 minute after the recovery

**Timepoint**  
1 minute after recovery admission  
**Method of measurement**  
Non-invasive automatic manometer

#### 11

**Description**  
Mean arterial blood pressure 3 minutes after the recovery  
**Timepoint**  
3 minutes after the recovery admission  
**Method of measurement**  
Non-invasive automatic manometer

#### 12

**Description**  
Mean arterial blood pressure 5 minutes after the recovery  
**Timepoint**  
5 minutes after the recovery admission  
**Method of measurement**  
Non-invasive automatic manometer

#### 13

**Description**  
Heart rate 1 minute after the blockade  
**Timepoint**  
1 minute after the blockade  
**Method of measurement**  
Pulse Oxymetry

#### 14

**Description**  
Heart rate 3 minutes after the blockade  
**Timepoint**  
3 minutes after the blockade  
**Method of measurement**  
Pulse Oxymetry

#### 15

**Description**  
Heart rate 5 minutes after the blockade  
**Timepoint**  
5 minutes after the blockade  
**Method of measurement**  
Pulse Oxymetry

#### 16

**Description**  
Heart rate 1 minute after the recovery  
**Timepoint**  
1 minute after the recovery admission  
**Method of measurement**  
Pulse Oxymetry

## 17

### **Description**

Heart rate 3 minutes after the recovery

### **Timepoint**

3 minutes after the recovery admission

### **Method of measurement**

Pulse Oxymetry

## 18

### **Description**

Heart rate 5 minutes after the recovery

### **Timepoint**

5 minutes after the recovery admission

### **Method of measurement**

Pulse Oxymetry

## **Intervention groups**

### 1

#### **Description**

Supraclavicular injection of 30ml Bupivacaine 0.5% +  
Administration of 25mcg/kg/min IV Propofol

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Supraclavicular injection of 20ml Bupivacaine 0.5% +  
Administration of 25mcg/kg/min IV Propofol

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Supraclavicular injection of 30ml Bupivacaine 0.5% +  
Administration of 25mcg/kg/min IV normal saline as  
placebo

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

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, The Vice-  
Chancellery for Research

#### **Full name of responsible person**

Mehrdad Sadri

#### **Street address**

5th floor, Central Building of Tehran University of  
Medical Sciences, Keshavarz Blvd

#### **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, The Vice-  
Chancellery for 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**

Tehran University of Medical Sciences, School of  
Medicine

##### **Full name of responsible person**

Mehrdad Sadri

##### **Position**

Medical student(Intern)

##### **Other areas of specialty/work**

##### **Street address**

Dormitory of Tehran University of Medical Sciences,  
16th St, Kargar Shomali St

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## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Shariati Hospital

##### **Full name of responsible person**

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**Position**

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**Postal code****Phone**

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Mehrdad Sadri

**Position**

Medical Student(Intern)

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**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*