

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The Evaluation of Effect of Addition of Different Doses of Verapamil to 1.5% Lidocaine on Sensory and Motor Axillary Block

#### Protocol summary

##### Summary

Background and Objectives: Studies showed that Verapamil as a Calcium channel blocker potentiates the analgesic effects of local anesthesia. In this study, we evaluated two doses of Verapamil (5 and 10 mg) in combination with Lidocaine on quality of local axillary blockage in comparison with placebo. Methods: Present study was a double blind randomized controlled clinical trial. Ninety two patients candidate for upper limb orthopedic and plastic surgery with axillary block will enroll the study and divide in three groups randomly. In group A, The patients will receive only Lidocaine 1.5%; in group B, The patients will receive Verapamil 5 mg plus Lidocaine 1.5%; and in group C, The patients will receive Verapamil 10mg plus Lidocaine 1.5%. Time of onset and duration of analgesia, sympathetic, sensory and motor blocks as well as hemodynamic changes will be evaluated in these three groups

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903094050N1**

Registration date: **2010-06-13, 1389/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-06-13, 1389/03/23

##### Registrant information

###### Name

Kambiz Sadegi

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7798 5238

###### Email address

fsadegi@put.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Investigator

###### Expected recruitment start date

2008-10-22, 1387/08/01

###### Expected recruitment end date

2009-10-23, 1388/08/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The Evaluation of Effect of Addition of Different Doses of Verapamil to 1.5% Lidocaine on Sensory and Motor Axillary Block

###### Public title

The Evaluation of Effect of Addition of Different Doses of Verapamil to 1.5% Lidocaine on Sensory and Motor Axillary Block

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

INCLUSION CRITERIA: 1) Upper extremities surgery including: Hand, Wrist & Forearm 2) Age upper than 18 & lower than 45 3) ASA I & II (American Society of Anesthesia 1 & 2 ) 4) Patient's consent to enter the study EXCLUSION CRITERIA: 1) Underlying diseases (Hypertension, Diabetes mellitus, Liver diseases, Renal diseases, Coagulopathy) 2) Addiction (opioids & Alcohol) 3) Not consent to enter the study 4) Morbid obesity

(weight more than 115 kg) 5) Allergy to local anesthetic drugs 6) Peripheral neuropathy 7) Local infection at injection site 8) Pregnancy

#### Age

From **18 years** old to **45 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **92**

#### 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

Iran University of Medical Sciences

##### Street address

Shahid Hemmat highway

##### City

Tehran

##### Postal code

#### Approval date

2009-09-01, 1388/06/10

#### Ethics committee reference number

45106

## Health conditions studied

### 1

#### Description of health condition studied

regional anesthesia

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Evaluation the time of onset & duration of sympathetic

block

#### Timepoint

Interval time: 0,5,10,15,20,30,45,60,75 minutes & every 15 minutes thereafter after blocking

#### Method of measurement

Sympathetic block: Alcohol test

### 2

#### Description

Evaluation the time of onset & duration of sensory & motor block

#### Timepoint

Interval time: 0,5,10,15,20,30,45,60,75 minutes & every 15 minutes thereafter after blocking

#### Method of measurement

Sensory block: Pin prick test/ Motor block: Fingers movement

### 3

#### Description

Evaluation the duration & quality of analgesia

#### Timepoint

Interval time: 0,5,10,15,20,30,45,60,75 minutes & every 15 minutes thereafter after blocking and for analgesia 2,4,6,12 ,24 hours in recovery and thereafter

#### Method of measurement

Analgesia: VAS score

## Secondary outcomes

### 1

#### Description

Blood pressure (systolic, diastolic)

#### Timepoint

Just before & after & 15, 30, 45, 60 minutes after axillary block & at the end of surgery and in recovery

#### Method of measurement

Non invasive blood pressure automatic monitoring

### 2

#### Description

mean arterial pressure

#### Timepoint

Just before & after & 15, 30, 45, 60 minutes after axillary block & at the end of surgery and in recovery

#### Method of measurement

Non invasive blood pressure automatic monitoring

### 3

#### Description

Heart Rate

#### Timepoint

Just before & after & 15, 30, 45, 60 minutes after axillary block & at the end of surgery and in recovery

#### Method of measurement

Non invasive blood pressure & Heart rate automatic monitoring

## Intervention groups

### 1

#### Description

Group A, The patients will receive only 34cc Lidocaine 1.5%

#### Category

Treatment - Other

### 2

#### Description

Group C, The patients will receive Verapamil 10 mg plus 34cc Lidocaine 1.5%

#### Category

Treatment - Drugs

### 3

#### Description

Group B, The patients will receive Verapamil 5mg plus 34cc lidocaine 1.5%.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hazrate Fatemeh Hospital

##### Full name of responsible person

##### Street address

Seied Jamaledine Asad Abadi St. - Tehran

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Hazrat Rasool Akram Hospital

##### Full name of responsible person

##### Street address

Sattar Khan St. - Niaiesh St.- Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

##### Street address

Shahid Hemmat highway

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran 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

Hazrat Rasool Akram Hospital

##### Full name of responsible person

Kambiz Sadegi

##### Position

Anesthesiology resident

##### Other areas of specialty/work

##### Street address

No.144 - BouAli St. - Tehran nou - Tehran

##### City

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##### Postal code

##### Phone

+98 21 7798 5238

##### Fax

##### Email

kamsadegi@yahoo.co.uk; fsadegi@put.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hazrat Rasool Akram Hospital

##### Full name of responsible person

Kambiz Sadegi

##### Position

Anesthesiology resident

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Hazrat Rasool Akram Hospital

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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*