

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

**Comparing the effectiveness of adding paracetamol and dexamethasone to lidocaine for intravenous block of upper extremity on severity of pain and period of painless during and after surgery.**

### Protocol summary

#### Summary

1) Objectives: Comparing the effectiveness of paracetamol and dexamethasone on the onset and duration of sensory and motor block, tourniquet pain and postoperative analgesia when these drugs are added to lidocaine 2) Design: Sixty patients undergoing upper limb surgery, as double-blind were randomized into four groups. 3) Setting and conduct: After the arrival of patient to the operating room, an intravenous line is established at dorsal vein of the operative hand. Then the proximal cuff of a pneumatic tourniquet that is placed around the upper arm, is inflated to 250 mmHg and IV regional anesthesia (IVRA) is done. Then the desired outcome variables are evaluated. 4) Participants including major eligibility criteria: patients 20 to 60 years old; candidate for upper extremity surgery and with ASA I or II are enrolled and patients with lidocaine allergy; infection; open fracture of limb; liver disease and addiction to opium and alcohol are excluded. 5) Intervention: All of the patients are received lidocaine (3 mg/kg) diluted with normal saline to a total volume of 40 mL. Group 1 received only lidocaine, group 2: lidocaine and dexamethason (8 mg), group 3: lidocaine and paracetamol (300 mg) and group 4: lidocaine and dexamethason (8 mg) and paracetamol (300 mg). 6) Main outcome measures: These include the following: the onset and duration of sensory and motor block, tourniquet pain and surgical site pain

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201209053104N2**  
Registration date: **2012-12-20, 1391/09/30**  
Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2012-12-20, 1391/09/30

#### Registrant information

##### Name

Mohammad Shabani

##### Name of organization / entity

Kerman Neuroscience Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1226 4196

##### Email address

shabani@kmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Kerman University of Medical Sciences

#### Expected recruitment start date

2012-04-03, 1391/01/15

#### Expected recruitment end date

2012-12-05, 1391/09/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the effectiveness of adding paracetamol and dexamethasone to lidocaine for intravenous block of upper extremity on severity of pain and period of painless during and after surgery.

## Public title

Comparing the effectiveness of adding paracetamol and dexamethasone to lidocaine for intravenous block of upper extremity on severity of pain and period of painless during and after surgery.

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 20 to 60 years old; candidate for upper extremity surgery and ASA I or II. Exclusion criteria: Lidocaine allergy; infection; open fracture of limb; liver disease and addiction to opium and alcohol

## Age

From **20 years** old to **60 years** old

## Gender

Both

## Phase

2-3

## 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

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Vice chancellor for research,  
Kerman University of Medical Sciences

##### Street address

Vice chancellor for research, Kerman University of  
Medical Sciences, Jahad Blvd, Somayye Crossroads,  
Shariaati St, Kerman

##### City

Kerman

##### Postal code

##### Approval date

2012-02-20, 1390/12/01

##### Ethics committee reference number

k/90/462

## Health conditions studied

### 1

#### Description of health condition studied

IV Regional Anesthesia

#### ICD-10 code

Y48.3

#### ICD-10 code description

Local anaesthetics

## Primary outcomes

### 1

#### Description

Surgical site pain

#### Timepoint

After the start of surgical process (at 5, 10, 15, 20, 30, 40 and 50 min) and after the end of surgery

#### Method of measurement

Visual Analogue Scale (VAS)

### 2

#### Description

Onset and duration of sensory and motor block

#### Timepoint

From the start of anesthetics injection to the end of operation

#### Method of measurement

Evaluate the patients response to needle hitting on surgical site and request of the patients to hand flexion and extension

### 3

#### Description

Tourniquet site pain

#### Timepoint

After applying the tourniquet and during surgery (at 5, 10, 15, 20, 30, 40 and 50 min)

#### Method of measurement

Visual Analogue Scale (VAS)

## Secondary outcomes

### 1

#### Description

Mean Arterial Pressure (MAP)

#### Timepoint

Before and after applying the tourniquet, during surgery (at 5, 10, 15, 20, 30, 40 and 50 min) and after opening the tourniquet

#### Method of measurement

By monitoring devices in the operating room (produced by Saadat Co)

### 2

#### Description

Heart Rate

#### Timepoint

Before and after applying the tourniquet, during surgery

(at 5, 10, 15, 20, 30, 40 and 50 min) and after opening the tourniquet

#### **Method of measurement**

By monitoring devices in the operating room (produced by Saadat Co)

### **3**

#### **Description**

Blood Oxygen Saturation

#### **Timepoint**

Before and after applying the tourniquet, during surgery (at 5, 10, 15, 20, 30, 40 and 50 min) and after opening the tourniquet

#### **Method of measurement**

By the pulse oximeter attached to the monitoring devices in the operating room (produced by Saadat Co)

## **Intervention groups**

### **1**

#### **Description**

Group 1: Patients are received lidocaine (3 mg/kg), that diluted with normal saline to a total volume of 40 mL (Injection time: 90 seconds), for regional anesthesia.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Group 2: Patients are received lidocaine (3 mg/kg) and dexamethason (8 mg), that diluted with normal saline to a total volume of 40 mL (Injection time: 90 seconds), for regional anesthesia.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Group 3: Patients are received lidocaine (3 mg/kg) and paracetamol (300 mg), that diluted with normal saline to a total volume of 40 mL (Injection time: 90 seconds), for regional anesthesia.

#### **Category**

Treatment - Drugs

### **4**

#### **Description**

Group 4: patients are received lidocaine (3 mg/kg) and dexamethason (8 mg) and paracetamol (300 mg), that diluted with normal saline to a total volume of 40 mL (Injection time: 90 seconds), for regional anesthesia.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Orthopedic operation room in Kerman Shahid Bahonar Hospital

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

Dr Mohammad Reza Doroudian

##### **Street address**

Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman

##### **City**

Kerman

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Vice chancellor for research, Kerman University of Medical Sciences

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

Dr. Malekpour Afshar

##### **Street address**

Vice chancellor for research, Kerman University of Medical Sciences, Jihad Blvd, Somayye Crossroads, Shariaati St, Kerman

##### **City**

Kerman

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Vice chancellor for research, Kerman 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**

Neuroscience Research Center, Kerman University of Medical Science

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

Mohammad Shabani

##### **Position**

PhD of Physiology/ Assistant Professor

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

##### **Street address**

Neuroscience Research Center, Kerman University of  
Medical Science, Jahad Blvd, Somayye Crossroads,  
Shariaati St, Kerman

**City**

Kerman

**Postal code**

**Phone**

+98 34 1226 4196

**Fax**

**Email**

shabanimoh@yahoo.com

**Web page address**

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Ali Sarkohi

**Position**

Resident in Anesthesiology

**Other areas of specialty/work**

**Street address**

Shahid Bahonar Hospital, Qarani St, Valiasr  
Crossroads, Shariaati St, Kerman

**City**

Kerman

**Postal code**

**Phone**

+98 34 1223 5011

**Fax**

**Email**

sarkoohiali@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Neuroscience Research Center, Kerman University of  
Medical Science

**Full name of responsible person**

Mohammad Shabani

**Position**

PhD of Physiology/ Assistant Professor

**Other areas of specialty/work**

**Street address**

Neuroscience Research Center, Kerman University of  
Medical Science, Jahad Blvd, Somayye Crossroads,  
Shariaati St, Kerman

**City**

Kerman

**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*