

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### Comparison of Postoperative Pain Management in Forearm Fracture with Lidocaine/Dexamethasone and Lidocaine/ Fentanyl through Axillary Block Technique

#### Protocol summary

##### Summary

Aim: To compare the analgesic efficacy of combined lidocaine/dexamethasone and lidocaine /fentanyl mixture following the operation of forearm fracture under axillary block. Materials and Methods: This is a clinical trial on 78 patients with forearm fracture that randomly divided into three groups. The axillary block was performed in the three groups by using lidocaine 40 ml and dH<sub>2</sub>O 2 ml (L Group), lidocaine 40 ml and dexamethasone 2 ml (LD group), and lidocaine 40 ml and fentanyl 2 ml ( F group)., Duration of sensory and motor block, pain (using VAS) and the total analgesic dose administered during 6 hrs after the surgery were recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012120711687N1**

Registration date: **2013-07-22, 1392/04/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-22, 1392/04/31

##### Registrant information

###### Name

Mahyar Seddighi

###### Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1334 4507

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Po. Box: 34185-745

##### Expected recruitment start date

2012-03-20, 1391/01/01

##### Expected recruitment end date

2012-08-22, 1391/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Postoperative Pain Management in Forearm Fracture with Lidocaine/Dexamethasone and Lidocaine/ Fentanyl through Axillary Block Technique

##### Public title

Comparison the analgesic efficacy of Lidocaine/Dexamethasone and Lidocaine/ Fentanyl in Forearm Fracture through Axillary Block

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Following inclusion criteria were considered: (a) Elective nature of surgery, presence of forearm fracture (b) Performance of surgery at Rajaei Hospital (c) Absence of underlying diseases such as coagulopathy, peripheral vascular diseases, and neuropathy (d) Patient's full agreement on performing axillary anesthesia (e) Lack of any history of allergy to local anesthetics (f) Lack of treatment with palliative drugs and those affecting the

CNS (g)Non-addict, and (h) Suitability of patients to be placed (classified) in ASA I&II classes. Also, the exclusion criteria employed were (a) operation duration of more than 90 min and b) the appearance of pain during the surgery

#### Age

From **20 years** old to **40 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **58**

#### 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 of Qazvin University of Medical Sciences

##### Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Po. Box: 34185-745

##### City

Qazvin

##### Postal code

#### Approval date

2012-03-06, 1390/12/16

#### Ethics committee reference number

28/20/6579

## Health conditions studied

### 1

#### Description of health condition studied

Analgesia following the operation of forearm fracture

#### ICD-10 code

S52.0, S52

#### ICD-10 code description

Fracture of upper end of ulna Incl.: Coronoid process

Elbow, NOS, Monteggia fracture-dislocation Olecranon process Proximal end. Fracture of upper end of radius Incl.: Head Neck Proximal end. Fracture of shaft of ulna. Fracture of shaft of radius. Fract

## Primary outcomes

### 1

#### Description

Total analgesic dose administered during 6 hrs after the surgery

#### Timepoint

During 6 hrs after the surgery

#### Method of measurement

Visual analogue scale

## Secondary outcomes

### 1

#### Description

Duration of sensory block

#### Timepoint

The time interval between the time of loss of pain sensation at forearm to reappearance of paresthesia

#### Method of measurement

Pin-prick test

### 2

#### Description

Time of duration of motor block

#### Timepoint

the time interval between the time of loss of pain sensation at forearm to complete recovery of motor function.

#### Method of measurement

Gripping force test

## Intervention groups

### 1

#### Description

Group 2 case:Lidocaine 1% (40 ml) + fentanyl 100 µg (2 ml).

#### Category

Treatment - Other

### 2

#### Description

Control group: Lidocaine 1% (40 ml) + dH2O (2 ml)

#### Category

Treatment - Drugs

### 3

#### Description

Group 1 case: Lidocaine 1% (40 ml) + dexamethasone (2 ml),

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hospital Rajayi

**Full name of responsible person****Street address**

Hospital Rajayi, Padegan street, Qazvin

**City**

Qazvin

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Qazvin University of Medical Sciences

**Full name of responsible person**

Aliakbar zinaloo

**Street address**

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**City**

Qazvin

**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, Qazvin 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**

Vice chancellor for research, Qazvin University of Medical Sciences

**Full name of responsible person**

Mahyar Seddighi

**Position**

Resident of Anesthesiology

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

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Mahyar Seddighi ; Siamak Yaqubi ,Marzieh Beigom Khezri

**Position**

Resident of Anesthesiology ; Assistant professor of Anesthesiology, Associate Professor of Anesthesiology

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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*