Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of Postoperative Pain Management in Forearm Fracture with Lidocaine/Dexamethasone and Lidacaine/ 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 dH2O 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

msedighi@qums.ac.ir

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 Lidacaine/ Fentanyl through Axillary Block Technique

Public title

Comparison the analgesic efficacy of Lidocaine/Dexamethasone and Lidacaine/ 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
Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Po. Box: 34185-745
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
Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Po. Box: 34185-745
City
Qazvin
Postal code
Phone
+98 28 1334 4507
Fax
Email
mahyarseddighi@ gmail.com ; dr_msa_md@ yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Vice chancellor for research, Qazvin University of Medical Sciences
Full name of responsible person
Mahyar Seddighi ; Siamak Yaqubi ,Marzieh Beigom Khezri
Position
Resident of Anesthesiology ; Assistant professor of Anesthesiology,Associate Professor of Anesthesio
Other areas of specialty/work
Street address
Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Po. Box: 34185-745
City
Qazvin
Postal code
Phone
00982813344507 ; 00982812239256
Fax
Email
mahyarseddighi@ gmail.com; siamakoo.c_yaqubi@ yahom ; dr_msa_md@ yahoo.com,mkhezri@qums.ac.ir
Web page address

Person responsible for updating data

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

Qazvin

Postal code

Phone

+98 28 1334 4507

Fax

Email

mahyarseddighi@ gmail.com ; dr_msa_md@ yahoo.com

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