

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation the effect of adding dexmedetomidine to lidocaine to improve quality of block and reduce the pain in patients who are candidates for fracture surgeries by supraclavicular block procedure under ultrasonic-guide.

Protocol summary

Summary

Goals: Evaluation the effect of adding dexmedetomidine to lidocaine in quality of supraclavicular blockade for forearm fracture surgeries. Method: In this randomized, double-blind, clinical trial sixty patients, aged 18-60 years, with ASA class I and II who are candidate for forearm fracture surgery without history of cardiovascular and liver disease, sensitivity to drugs used in study, use alfa-2 adrenergic and/or analgesic before the surgery, patients with neurologic and/or psychologic disorders will be studied. After obtaining the written informed consent from patients, they will be allocated in two group A and B randomly with Using random permutation blocks with a block size of 4 (using a table of random permutations). Group A will receive 30 ml solution containing lidocaine 1% plus isotonic normal saline. Group B will receive 30 ml solution containing lidocaine 1 %+ dexmedetomodine (1mcg/kg). The supraclavicular block will be performed using ultrasonographic guide. Onset and duration of sensory and motor block, time to first analgesic request and total analgesic intake in first 24 hour after surgery will be compared in our study. Sensor block level will be assessed by pinprick assessing dermatomes of sensory regions using 3-point scale. The intensity of motor block will be assessed using the modified bromage scale. The pain during surgery and postoperative will be assessed using VAS score. The side effects will be assessed during surgeries and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040433210N1**

Registration date: **2017-06-25, 1396/04/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Amir hosein Baniahmad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of adding dexmedetomidine to

lidocaine to improve quality of block and reduce the pain in patients who are candidates for fracture surgeries by supraclavicular block procedure under ultrasonic-guide.

Public title

The effect of adding dexmedetomidine to lidocaine on nerve block.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients at the age of 18-60 years with ASA physical status I or II who are candidate for forearm surgery. Exclusion criteria : History of cardiovascular and liver diseases; Sensitivity to drugs used in study; Use alfa-2 adrenergic and/or analgesic before the surgery; Patients with neurological and/or psychological disorders.

Age

No age limit

Gender

Both

Phase

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

Used

Assignment

Parallel

Other design features

The study will be done randomly with Using random permutation blocks with a block size of 4 (using a table of random permutations).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan boulevard

City

Ahvaz

Postal code

6135715794

Approval date

2017-04-15, 1396/01/26

Ethics committee reference number

IR.AJUMS.REC.1396.20

Health conditions studied

1

Description of health condition studied

Peripheral nerve block

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Onset of sensory block

Timepoint

5-10-15 -30 minute intervals after injection.

Method of measurement

Physical Examination by Physician (Pinprick test).

2

Description

Onset of motor block.

Timepoint

5, 10, 15 and 30 minutes after injection

Method of measurement

Physical Examination by Physician (modified bromage scale).

3

Description

Duration of sensory block

Timepoint

Untile patients analgesic request.

Method of measurement

Physical Examination by Physician.

4

Description

Duration of motor block

Timepoint

Untile start movement around median, radial, and ulnar nerves.

Method of measurement

Physical Examination by Physician

5

Description

The time of first Analgesic Request

Timepoint

One hour intervals untile first 24 hours

Method of measurement

Patient's file

6

Description

Analgesic received in 24 hours

Timepoint

24 hours after surgery

Method of measurement

Patient's documents

Secondary outcomes

1

Description

Heart Rate per minute

Timepoint

Before block (base line) then every 5 minutes after block, then every 5 minutes after starting surgery till end of surgery and then every 15 minute till Departure time from recovery.

Method of measurement

Cardiac Monitoring Device

2

Description

Arterial Oxygen Saturation

Timepoint

Before block (base line) then every 5 minutes after block, then every 5 minutes after starting surgery till end of surgery and then every 15 minute till Departure time from recovery.

Method of measurement

Continious Pulse Oximetry

3

Description

Mean Arterial Pressure

Timepoint

Before block (base line) then every 5 minutes after block, then every 5 minutes after starting surgery till end of surgery and then every 15 minute till Departure time from recovery.

Method of measurement

By non-invasive Manometer device(millimeter Hg).

Intervention groups

1

Description

Control group: Injection of 30 milliliter solution containing isotonic Normal Saline plus 1 percent Lidocaine under ultrasound guidance after sensory and motor block beginning.

Category

Treatment - Drugs

2

Description

Intervention group: Injection of 30 milliliter solution

containing 1 mcg per kg dexmedetomidine plus 1 percent Lidocaine under ultrasound guidance after sensory and motor block beginning.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Amir Hosein Baniahmad

Street address

Azadegan street

City

Ahvaz

2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Amir Hosein Baniahmad

Street address

Amanieh

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Behzad Sharif Makhmalzadeh

Street address

Golestan boulevard

City

Ahvaz

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 of Ahvaz Jundishapur 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

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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