Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
Name of organization / entity
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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