Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Adding of Dexmedetomidine to Lidocaine in Supraclavicular Block undr ultrasound guid On Upper Limb Fracture Surgery

Protocol summary

Summary

(1) Objectives: Is the Supraclavicular Block Duration Can Be Prolonged By adding Dexmedetomidine to Lidocaine? (2) Design, This study is randomized double-blind clinical trial study. (3) Setting and Conduct: Patients are randomly allocated into two groups, group D, receiving 30 ml of 1.5% lidocaine with 1 mcg/kg of dexmedetomidine and group C, receiving 30 ml of 1.5% lidocaine with isotonic normal saline. Sensory and motor block were assessed by pin prink and bromage scale every 3 minutes, respectively until complete block is defined. Intraoperative monitoring of blood pressure, heart rate and verbal rating scale will performed at an interval of 5 minutes until 15 minutes then every 15minutes until 1houre and then every 30minutes until the sensory and motor block has completely worn off. Finally, patients' data in two groups will compared. (4) Participants including major eligibility criteria: The Inclusion criteria are age between 18-60 years old with ASA class 1-2 who will candidate for radial or ulnar fracture surgery. The exclusion criteria will consist of patients on adrenoreceptor agonist, known hypersensitivity to local anesthetic drugs. (5) Intervention: Patients are randomly allocated into two groups, group D, will receive 30 ml of 1.5% lidocaine with 1 mcg/kg of dexmedetomidine and group C, will receive 30 ml of 1.5% lidocaine with isotonic normal saline. (6) main outcome measures (variables): Primary Outcome; Duration of Motor and Sensory Blockade. Secondary Outcome:heart rate , Blood Pressure and Nausea ,Vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607276280N9**
Registration date: **2016-09-09, 1395/06/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-09-09, 1395/06/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Guilan University of Medical Sciences

Expected recruitment start date

2016-08-21, 1395/05/31

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adding of Dexmedetomidine to Lidocaine in Supraclavicular Block undr ultrasound guid On Upper Limb Fracture Surgery

Public title

Survey of Dexmedetomidine Effect On Supraclavicular Block Duration

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:the patients between 18-60 years old;ASA class 1-2 ; radial and ulnar fracture surgery.
Exclusion criteria: Patients on adrenoreceptor agonist ;or antagonist therapy; known hypersensitivity to local anaesthetic drugs.
Age
From **18 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
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice Chancellor For Research of Guilan University Of Medical Sciences
Street address
Shahid Beheshti Highway
City
Rasht
Postal code
Approval date
2016-06-21, 1395/04/01
Ethics committee reference number
IR.GUMS.REC.1395.112

Health conditions studied

1

Description of health condition studied
upper limb fracture
ICD-10 code
S52.4
ICD-10 code description
Fracture of shafts of both ulna and radius

Primary outcomes

1

Description
Duration of Motor and Sensory Blockade
Timepoint
Every 5minutes until 15 minutes then every 15minutes until one houre and then every 30minutes until patient undemand analgesia
Method of measurement
Numerical Rating Scale Questionare

Secondary outcomes

1

Description
Blood Pressure,Heart Rate,Nausea and Vomiting .
Timepoint
Every 5minutes until 15 minutes then every 15minutes until one houre and then every 30minutes until the sensory and motor block has completely worn off.
Method of measurement
questionare ,heart rate ,blood pressure ,nausea and vomiting .

2

Description
Heart rate
Timepoint
هر 5دقیقه تا 15 دقیقه سپس هر 15 دقیقه تا یکساعت و بدنبال آن هر 30دقیقه تا برگشت کامل بلوک حسی و حرکتی
Method of measurement
ECG monitoring

Intervention groups

1

Description
Dexmedetomidine Adding Lidocaine in Supraclavicular block
Category
Treatment - Drugs

2

Description
Isotonic Salin Adding Lidocaine in Supraclavicular Block
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Poursina Hospital
Full name of responsible person
Mohammad Haghighi
Street address
Rasht , Parastar Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research of Guilan University OfMedical Sciences
Full name of responsible person
Dr Shadman Nemati
Street address
Shahid Beheshti Highway
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Rasht
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 Guilan University OfMedical 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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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