

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Adding of Dexmedetomidine to Lidocaine in Supraclavicular Block under ultrasound guidance for 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 prick and Bromage scale every 3 minutes, respectively until complete block is defined. Intraoperative monitoring of blood pressure, heart rate and verbal rating scale will be performed at an interval of 5 minutes until 15 minutes then every 15 minutes until 1 hour and then every 30 minutes until the sensory and motor block has completely worn off. Finally, patients' data in two groups will be compared. (4) Participants including major eligibility criteria: The inclusion criteria are age between 18-60 years old with ASA class 1-2 who will be candidates for radial or ulnar fracture surgery. The exclusion criteria will consist of patients on adrenergic 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

Name

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Name of organization / entity

Guilan University of Medical Sciences

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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 under ultrasound guidance for 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 adrenoceptor 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 hour 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 hour 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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manesthesist@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor For Research of Guilan University

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Full name of responsible person

Dr Shadman Nemati

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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**

Guilan University Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

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Fax**Email****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