Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparison of the effect of Dexmedetomidine on the onset and duration of sensory block , using different dosages of Bupivacaine in ultrasound guided Brachial Plexus (Supraclavicular) block for patients undergoing upper limb surgery.

Protocol summary

Summary

Study design : Clinical trial-randomized-double blinded Population under study : Patients undergoing upper limb surgery at Shariati hospital. Inclusion criteria : age : 20-50, BMI below 35, ASA class I,II,III ,Negative previous history for drug reaction, Patients full informed consent. exclusion criteria : Unsuccessful block , Surgeries longer than 180 minutes,patient's refusal, Any complications during surgery, indication for general anesthesia . Group A : Candidates for supraclavicular block receiving 30 ml Bupivacaine 0.5% + Dexmedetomidine IV infusion 0.5 mcg/kg/min IV Group B :Candidates for supraclavicular block receiving 20 ml Bupivacaine 0.5% + Dexmedetomidine 0.5 mcg/kg/min IV Group C : Candidates for supraclavicular block receiving 30 ml bupivacaine 0.5 % +Normal Saline 0.5mcg/kg/min IV. Duration and onset of sensory and motor block will be compared in our study groups. The patients will be randomized after full informed consent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112331061N1**
Registration date: **2017-01-31, 1395/11/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-31, 1395/11/12

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of medical sciences. Vice chancellor of research.

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of Dexmedetomidine on the onset and duration of sensory block , using different dosages of Bupivacaine in ultrasound guided Brachial Plexus (Supraclavicular) block for patients undergoing upper limb surgery.

Public title

Identifying the effect of dexmedetomidine on the dosage of Bupivacaine in brachial plexus block.

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion Criteria :ages 20 to 50; BMI below 35;No history of drug reaction;Patients' informed consent Exclusion Criteria : Unsuccessful Block;The operation lasts for more than 180 minutes; Patients refusal; Any complication;Necessity for general anesthesia.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **69**
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
Tehran University of medical sciences
Street address
level 4th, number 23, 16th azar street, Keshavarz blv
City
Tehran
Postal code
Approval date
2016-11-21, 1395/09/01
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.1065

Health conditions studied

1

Description of health condition studied
Supraclavicular block- local anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Onset of sensory block
Timepoint
During the intervention
Method of measurement
Digital chronometer

2

Description
Onset of motor block
Timepoint
During the intervention
Method of measurement
Digital chronometer

3

Description
Duration of sensory block
Timepoint
During the intervention
Method of measurement
Digital chronometer

4

Description
Duration of motor block
Timepoint
During the intervention
Method of measurement
Digital chronometer

5

Description
Dosage of Bupivacaine 0.05%
Timepoint
During the intervention
Method of measurement
milliliters

Secondary outcomes

1

Description
Mean atrial pressure 1 minute after the block
Timepoint
1 minute after the block
Method of measurement
Digital non invasive sphygmomanometer

2

Description
Mean atrial pressure 3 minute after the block
Timepoint
3 minute after the block
Method of measurement

Digital non invasive sphygmomanometer

3

Description
Mean atrial pressure 5 minute after the block
Timepoint
5 minute after the block
Method of measurement
Digital non invasive sphygmomanometer

4

Description
Pulse rate one minute after the block
Timepoint
1 minute after the block
Method of measurement
Pulse oximeter

5

Description
Pulse ratethree minute after the block
Timepoint
3 minute after the block
Method of measurement
Pulse oximeter

6

Description
Pulse rate five minute after the block
Timepoint
5 minute after the block
Method of measurement
Pulse oximeter

Intervention groups

1

Description
Intervention group 2 : Patients candidate for supraclavicular injection, 20 ml of Bupivacaine 0.5% IV + 0.5 mcg/kg/min dexmedetomidine IV.
Category
Treatment - Drugs

2

Description
Control group : Patients candidate for supraclavicular injection, 30 ml of Bupivacaine 0.5% IV + Placebo Normal Saline IV infusion 0.5mcg/kg/min .
Category
Treatment - Drugs

3

Description
Intervention group 1 : Patients candidate for supraclavicular injection, 30 ml of Bupivacaine 0.5% IV + 0.5 mcg/kg/min dexmedetomidine IV.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Reza Atef Yekta
Street address
Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Masoud Younesian , Vice Chancellor of research
Street address
Keshavarz Blvd, Ghods street, Head quarters,6th floor
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Nazanin Sheibani
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Medical Student
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Person responsible for scientific inquiries

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Reza Atef Yekta

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Person responsible for updating data

Contact

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