

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Name

Nazanin Sheibani

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of medical sciences. Yice 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 rate three 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

Position

Medical Student

Other areas of specialty/work

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Reza Atef Yekta

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Web page address

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