Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Studying the effect of intravenous Propofol used with two different volumes of local anesthetic(Bupivacaine) on sensory and motor blockade in patients undergoing upper limb surgery by sonographic supraclavicular brachial plexus block approach

Protocol summary

Summary

This study is performed as a controlled randomized clinical trial in order to sedate with a better quality by lower volumes of local anesthetic(Bupivacaine) in patients undergoing upper limb surgery by sonographic supraclavicular brachial plexus blockade. Inclusion and exclusion criteria are applied. Inclusion Criteria are: ages between 20 and 50; ASA classes: I,II,III; BMI under 35; absence of the history of drug induced hypersensitivity; taking of informed consent. Exclusion Criteria are: failure of supraclavicular blockade; need to general anesthesia. Supraclavicular blockade is performed by sonographic guidance after taking informed consent from the patients and randomized division of the patients into 3 different groups based on the use of Propofol or placebo with different volumes of local anesthetic(Bupivacaine). Demographic information and pain score is obtained by interviewing the patients. The onset and duration of sensory and motor blockage is determined by Pinprick Test and Lovett Rating Scale. Hemodynamic information is obtained by monitoring the patients by digital equipments. The onset and duration of sensory and motor blockage is compared in these 3 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021430855N1**
Registration date: **2017-02-14, 1395/11/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-14, 1395/11/26

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, The Vice-Chancellery for Research

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of intravenous Propofol used with two different volumes of local anesthetic(Bupivacaine) on sensory and motor blockade in patients undergoing upper limb surgery by sonographic supraclavicular brachial plexus block approach

Public title

The Effect of Intravenous Propofol on Local Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Ages between 20 and 50; ASA classes: I,II,III; BMI under 35; Absence of the history of drug induced hypersensitivity; Taking of informed consent
Exclusion Criteria: Failure of supraclavicular blockade; Need to 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: **90**

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

Research Ethics Committee of Tehran University of Medical Sciences, School of Medicine

Street address

Plate 23, 16th of Azar St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2016-11-22, 1395/09/02

Ethics committee reference number

medicine2IR.TUMS.MEDICINE.REC.1395.1082

Health conditions studied

1

Description of health condition studied

Supraclavicular Blochade of the Brachial Plexus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of Motor Blockage

Timepoint

During and after the intervention

Method of measurement

Physical examination by the physician

2

Description

Duration of Sensory Blockage

Timepoint

During and after the intervention

Method of measurement

Physical examination by the physician

3

Description

Onset of the Motor Blockage

Timepoint

During the intervention

Method of measurement

Physical examination by the physician

4

Description

Onset of the Sensory Blockage

Timepoint

During the intervention

Method of measurement

Physical examination by the physician

Secondary outcomes

1

Description

Patient's feeling of pain

Timepoint

After the intervention in the same admission

Method of measurement

Visual Analogue Scale (VAS)

2

Description

The measure of motor blockade

Timepoint

During and after the intervention

Method of measurement

Lovett Rating Scale

3

Description

The time of the first opioid request by the patient

Timepoint

After the intervention in the same admission

Method of measurement

By using PCA(Patient Controlled Anaesthesia)

4

Description

Administered opioid dosage in 24 hours

Timepoint

After the intervention in the same admission

Method of measurement

Patient Medical Document

5

Description

Duration of the surgery

Timepoint

During the intervention

Method of measurement

Patient Medical Document

6

Description

Nausea and vomiting after the surgery

Timepoint

After the intervention in the same admission

Method of measurement

Asking the patient

7

Description

Mean arterial blood pressure 1 minute after the blockade

Timepoint

1 minute after the blockade

Method of measurement

Non-invasive automatic manometer

8

Description

Mean arterial blood pressure 3 minutes after the blockade

Timepoint

3 minutes after the blockade

Method of measurement

Non-invasive automatic manometer

9

Description

Mean arterial blood pressure 5 minutes after the blockade

Timepoint

5 minutes after the blockade

Method of measurement

Non-invasive automatic manometer

10

Description

Mean arterial blood pressure 1 minute after the recovery

Timepoint

1 minute after recovery admission

Method of measurement

Non-invasive automatic manometer

11

Description

Mean arterial blood pressure 3 minutes after the recovery

Timepoint

3 minutes after the recovery admission

Method of measurement

Non-invasive automatic manometer

12

Description

Mean arterial blood pressure 5 minutes after the recovery

Timepoint

5 minutes after the recovery admission

Method of measurement

Non-invasive automatic manometer

13

Description

Heart rate 1 minute after the blockade

Timepoint

1 minute after the blockade

Method of measurement

Pulse Oxymetery

14

Description

Heart rate 3 minutes after the blockade

Timepoint

3 minutes after the blockade

Method of measurement

Pulse Oxymetery

15

Description

Heart rate 5 minutes after the blockade

Timepoint

5 minutes after the blockade

Method of measurement

Pulse Oxymetery

16

Description

Heart rate 1 minute after the recovery

Timepoint

1 minute after the recovery admission

Method of measurement

Pulse Oxymetery

17

Description
Heart rate 3 minutes after the recovery
Timepoint
3 minutes after the recovery admission
Method of measurement
Pulse Oxymetery

18

Description
Heart rate 5 minutes after the recovery
Timepoint
5 minutes after the recovery admission
Method of measurement
Pulse Oxymetery

Intervention groups

1

Description
Supraclavicular injection of 30ml Bupivacaine 0.5% + Administration of 25mcg/kg/min IV Propofol
Category
Treatment - Drugs

2

Description
Supraclavicular injection of 20ml Bupivacaine 0.5% + Administration of 25mcg/kg/min IV Propofol
Category
Treatment - Drugs

3

Description
Supraclavicular injection of 30ml Bupivacaine 0.5% + Administration of 25mcg/kg/min IV normal saline as placebo
Category
Treatment - Drugs

Recruitment centers

1

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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, The Vice-Chancellery for Research
Full name of responsible person
Mehrdad Sadri
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5th floor, Central Building of Tehran University of Medical Sciences, Keshavarz Blvd
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, The Vice-Chancellery for Research
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

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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