

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

studying the effects of adding dexmedetomidine to bupivacaine on supraclavicular nerve block in upper limb orthopedic surgery among chronic opium abusers compared with non users.

Protocol summary

Summary

This study aims to evaluate the effect of adding perineural Dexmethetomidine to Bupivacaine on the duration of supraclavicular nerve block in chronic opium abusers compared with non abusers. Inclusion criteria: ASA class I and II; male; current smokers; aged between 18-60; scheduled for elective upper limb orthopedic surgery under supraclavicular nerve block. Exclusion criteria: Patients with any contraindications to supraclavicular nerve block; addiction to any substance other than opium and cigarettes; known history of cardiac, respiratory, or psychological diseases; block failure of any nerve distributions (i.e. if the patient feel pain in those regions) 84 patients will be randomly assigned into 4 groups, 21 in each group: groups A and B without a history of opium abuse ,and groups C and D with a history of opium abuse which all of their members were scheduled for elective upper limb orthopedic surgery, and then these groups fall into two categories: to block, the first category (including groups A & C) receives only 30 ml bupivacaine and the second one (including groups B & D) receives the 30 ml bupivacaine in combination with an additional 20 µg Dexmedetomidine. An ultrasound-guided technique will be applied to perform upper extremity brachial plexus blockade. The onset and duration of sensory and motor blocks will be recorded and compared between the four groups. Primary outcome variables: sensory block onset; sensory block duration; motor block onset; motor block duration

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112631107N1**
Registration date: **2017-05-24, 1396/03/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-24, 1396/03/03

Registrant information

Name

Maryam Taheri

Name of organization / entity

Tehran University Of Medical Science

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-04-04, 1397/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

studying the effects of adding dexmedetomidine to bupivacaine on supraclavicular nerve block in upper limb orthopedic surgery among chronic opium abusers

compared with non users.

Public title

evaluating the effect of an anesthetic agent on the duration of anesthesia and analgesia among chronic opium abusers

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: (ASA) physical status class I and II; male; current smokers; aged between 18-60; scheduled for elective upper limb orthopedic surgery under supraclavicular nerve block. exclusion criteria: Patients with any contraindications to supraclavicular nerve block; patients with addiction to any substance other than opium and cigarettes; patients with known history of cardiac, respiratory, or psychological diseases; block failure of any nerve distributions (i.e. if the patient feel pain in those regions), the patient will be excluded from the study, even when the block is adequate to perform the operation.

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

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 the Medical Faculty of Tehran University of Medical Sciences

Street address

Professional Doctoral Theses Unite, Ground Floor, Education Building, Faculty of Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2016-10-05, 1395/07/14

Ethics committee reference number

medicine2IR.TUMS.MEDICINE.REC.1395.729 1395/07/14

Health conditions studied

1

Description of health condition studied

Regional anesthesia

ICD-10 code

T41.3, Y48

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

sensory block onset

Timepoint

sensory block will be checked continuously after completion of injection until complete sensory and motor block.

Method of measurement

pinprick test and a verbal rating scale from 100% (normal sensation) to 0 (no sensation).

2

Description

sensory block duration

Timepoint

after complete sensory block and every 15 minutes following the end of operation.

Method of measurement

pinprick test and a verbal rating scale from 100% (normal sensation) to 0 (no sensation).

3

Description

motor block onset

Timepoint

motor block will be checked continuously after completion of injection until complete motor block.

Method of measurement

Lovett rating scale

4

Description

motor block duration

Timepoint

after complete motor block and every 15 minutes following the end of operation

Method of measurement

the Lovett rating scale

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

continuously monitoring while the surgery is performing

Method of measurement

manometer

2

Description

Diastolic blood pressure

Timepoint

continuously monitoring while the surgery is performing

Method of measurement

manometer

3

Description

Heart rate

Timepoint

continuously monitoring while the surgery is performing

Method of measurement

Monitoring

4

Description

Respiratory depression

Timepoint

continuously monitoring while the surgery is performing

Method of measurement

O2 saturation & Respiratory Rate

5

Description

Drug consumption in the 24 hours after surgery

Timepoint

patient need

Method of measurement

Medical records

Intervention groups

1

Description

second intervention group receives 30 ml hyperbaric bupivacaine along with 20 micro gram dexmedetomidine to perform regional anesthesia

Category

Treatment - Drugs

2

Description

first intervention group receives 30 ml hyperbaric bupivacaine along with 2 ml saline as placebo to perform

regional anesthesia

Category

Treatment - Drugs

3

Description

second control group receives 30 ml hyperbaric bupivacaine along with 20 micro gram dexmedetomidine to perform regional anesthesia

Category

Treatment - Drugs

4

Description

first control group receives 30 ml hyperbaric bupivacaine along with 2 ml saline as placebo to perform regional anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr Maryam Taheri

Street address

Shariati hospital, Jalal-e-Al-e-Ahmad high way, district 6, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences Vice Chancellor Of Research

Full name of responsible person

Dr Shahin Akhond Zade Basti

Street address

Room 206, First Floor, Building 1, Medicine Faculty, Tehran university of medical science

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 Vice Chancellor Of 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*

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