Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Shariati Hospital, Anesthesilogy Department
Full name of responsible person
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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