Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Bupivacaine alone compared to Bupivacaine with Dexmedetomidine on patients' hemodynamic in orthopedic surgery of upper limb in Shariati Hospital in 95-96

Protocol summary

Summary

(1) Objectives: Compare hemodynamic changes in studied patients. (2) Design: Randomized, Double blinded, Controlled with Placebo, One center, 2-3 Trial phase. (3) Setting and conduct: Two groups of 49 people (98 totally) that supraclavicular block is applied on them based on sonography guidance. Through interviews with patients, demographic information and pain scores collected. Information on the onset and duration of sensory and motor block was obtained by Pinprick Test and Lovett Rating Scale. Hemodynamic data was extracted from the monitoring device. (4) Participants including major eligibility criteria: Major inclusion criteria: age 20-50 year-old; American Society of Anesthesiologists class I,II; Body Mass Index less than 35. Major exclusion criteria: Failed to supraclavicular block; Prolonged surgery more than 180 minutes; Liver Disease; Diabetes Mellitus; Hypertension; taking Blood pressure medication. (5) Intervention: In intervention group 30 milliliters of 5 percent Bupivacaine and 20 micro grams of Dexmedetomidine; and in controlled group 30 milliliters of 5 percent Bupivacaine and 0.2 milliliters Normal Saline (as placebo) for supraclavicular block will be used. (6) Main outcome measures (variables): The numerical values of the Mean Arterial Pressure (as a primary out come), Heart Rate per minute, the Arterial Oxygen Saturation, Respiratory Rate per minute, Sensory and Motor block Onset and Duration of Sensory and Motor block (as secondary outcomes) in the two groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112631108N1**

Registration date: **2017-03-04, 1395/12/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name

Siamak Yoosefi Khanghah

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Vice Chancellor of Research

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Bupivacaine alone compared to Bupivacaine with Dexmedetomidine on patients' hemodynamic in

orthopedic surgery of upper limb in Shariati Hospital in 95-96

Public title
The effect of Bupivacaine with and without Dexmedetomidine on patients' hemodynamic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:20-50 year old; Body Mass Index less than 35; American Society of Anesthesiologists class I,II; No Allergic drug history; Patient satisfaction and fill out the consent form Exclusion Criteria: Failed to supraclavicular block; Prolonged surgery more than 180 minutes; Cancel patients; Liver Disease; Diabetes Mellitus; Hypertension; taking Blood pressure medication; taking beta blocker medication; The incidence of surgical complication during surgery; Requires general anesthesia
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **98**
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 Unit, Ground Floor, Education Building, Faculty of Medicine, Tehran University of Medical Sciences, Pour Sina Street, District 6, Tehran
City
Tehran
Postal code
Approval date
2017-01-29, 1395/11/10
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.1566 1395/11/10

Health conditions studied

1

Description of health condition studied
Regional Anesthesia
ICD-10 code
y48.3
ICD-10 code description
Local Anesthetics

Primary outcomes

1

Description
Mean Arterial Pressure
Timepoint
In recovery (base line) then every 5 minutes after block, then every 5 minutes after starting surgery for 30 minutes, then every 15 minutes till end of surgery and in Departure time from recovery
Method of measurement
Millimeter Hg (Mercury) by non-invasive Manometer device

Secondary outcomes

1

Description
Heart Rate per minute
Timepoint
In recovery (base line) then every 5 minutes after block, then every 5 minutes after starting surgery for 30 minutes, then every 15 minutes till end of surgery and in Departure time from recovery
Method of measurement
Cardiac Monitoring Device

2

Description
Respiratory Rate per minute
Timepoint
In recovery (base line) then every 5 minutes after block, then every 5 minutes after starting surgery for 30 minutes, then every 15 minutes till end of surgery and in Departure time from recovery
Method of measurement
Monitoring Device

3

Description
Arterial Oxygen Saturation
Timepoint
In recovery (base line) then every 5 minutes after block,

then every 5 minutes after starting surgery for 30 minutes, then every 15 minutes till end of surgery and in Departure time from recovery

Method of measurement

Continious Pulse Oximetry

4

Description

Narcotics received in 24 hours

Timepoint

Total drug intake in first 24 hours after surgery

Method of measurement

Patient's file

5

Description

Time to First Analgesic Request

Timepoint

Time to first analgesic request

Method of measurement

Patient's file

6

Description

Onset of Sensory Block

Timepoint

5-10-15 -30 minute intervals after injection

Method of measurement

Physical Examination by Physician (Pinprick test)

7

Description

Onset of Motor Block

Timepoint

5-10-15 -30 minute intervals after injection

Method of measurement

Physical Examination by Physician (Lovett Rating Scale)

8

Description

Duration of Sensory Block

Timepoint

Every 10 minutes after full sensory block until complete return of sensation

Method of measurement

Physical Examination by Physician (Pinprick test)

9

Description

Duration of Motor Block

Timepoint

Every 10 minutes after full motor block until complete return of motor function

Method of measurement

Physical Examination by Physician (Lovett Rating Scale)

Intervention groups

1

Description

Supraclavicular injection of 30 milliliter 0.5 percent Bupivacaine + 20 microgram Dexmedetomidine solution with ultrasound guidance

Category

Treatment - Drugs

2

Description

Supraclavicular injection of 30 milliliter 0.5 percent Bupivacaine + 0.2 milliliter Normal Saline solution (As a Placebo) with ultrasound guidance

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Siamak Yoosefi Khanghah

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad intersection, NorthKargar Avenue

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 Zadeh Basti

Street address

Room 206, First Floor, Office Building, Faculty of Medicine, Tehran University of Medical Sciences, Pour Sina Street, District 6, Tehran

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

Person responsible for general inquiries

Contact

Name of organization / entity

Shariati Hospital, Anesthesiology Department

Full name of responsible person

Dr. Siamak Yoosefi Khanghah

Position

Medical Student

Other areas of specialty/work

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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