

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation the effect of dexmedetomidine with bupivacaine and bupivacaine alone on postoperative pain in upper limb orthopedic surgery with supraclavicular block

Protocol summary

Study aim

The purpose of this study will be to assess the effect of dexmedetomidine with bupivacaine and bupivacaine alone on postoperative pain in upper limb orthopedic surgery with supraclavicular block

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 3-2.

Settings and conduct

In Urmia Imam Khomeini hospital operating room after the onset time of the sensory and motor block, the duration of the sensory and motor block and postoperative pain will be measured.

Participants/Inclusion and exclusion criteria

inclusion criteria: aged 20-60 years old; American Society of Anesthesiologists physical status classification I; general anesthesia. Exclusion criteria: history of cardiovascular disease; history of respiratory disease; history of renal disease; history of liver disease; pregnancy; allergy to the drugs studied; contraindication of supraclavicular block; coagulopathy.

Intervention groups

In Intervention group patients will be received 39 ml of bupivacaine 0.25% with 1 ml (1 µg/kg) dexmedetomidine. In control group patients will be received 39 ml of bupivacaine 0.25% with 1 ml saline 0.9%.

Main outcome variables

Duration of the sensory and motor block; post operative pain

General information

Reason for update

Correction of the date of illness getting patient

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N15**

Registration date: **2019-05-28, 1398/03/07**

Registration timing: **prospective**

Last update: **2020-05-29, 1399/03/09**

Update count: **1**

Registration date

2019-05-28, 1398/03/07

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

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sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of dexmedetomidine with

bupivacaine and bupivacaine alone on postoperative pain in upper limb orthopedic surgery with supraclavicular block

Public title

Evaluation the effect of dexmedetomidine with bupivacaine on postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 20-60 years old American Society of Anesthesiologists physical status classification I General anesthesia

Exclusion criteria:

History of cardiovascular disease History of respiratory disease History of renal disease History of liver disease Pregnancy Allergy to the drugs studied Contraindication of supraclavicular block Coagulopathy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups of Dexmedetomidine and Bupivacaine (group D) and Bupivacaine (group B) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist will be unaware of which patient will be assigned to which group. Syringes will be identical and only the operating room nurse will know about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-09-05, 1397/06/14

Ethics committee reference number

IR.UMSU.REC.1397.181

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes

1

Description

Pain

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

2

Description

Duration of the sensory block

Timepoint

From the onset of the sensory block until the onset of the first pain after surgery

Method of measurement

Pinprick

3

Description

Duration of the motor block

Timepoint

Since full paralysis of limb until complete restoration of limb movement

Method of measurement

Bromage scale

Secondary outcomes

1

Description

Mean Arterial Blood Pressure

Timepoint

During surgery

Method of measurement

None Invasive Blood Pressure

2

Description

Mean pulse Rate

Timepoint

During surgery

Method of measurement

Electrocardiogram

3

Description

Pentazocine consumption

Timepoint

After transferring the patient to the ward in the first 24 hours

Method of measurement

milligram

Intervention groups

1

Description

Intervention group: Patients in Group dexmedetomidine will be received 39 ml of bupivacaine 0.25% with 1 ml (1 µg/kg) dexmedetomidine

Category

Prevention

2

Description

Control group: Patients in Group bupivacaine will be received 39 ml of bupivacaine 0.25% with 1 ml saline 0.9%

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital, C operating room

Full name of responsible person

Shahryar Sane

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Modarres Boulevard, Ershad Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Ormia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available