

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparative evaluation of effects of adding Dexmedetomidine, Dexamethasone and Na Bicarbonate to Ropivacaine in ultrasound-guided supraclavicular block on the quality of the block in orthopedic surgery

Protocol summary

Study aim

Determining the effect of adding dexmedetomidine, dexamethasone, and sodium bicarbonate to ropivacaine in the ultrasound-guided supraclavicular block on the quality of the block in orthopedic surgery

Design

A clinical trial with the control group, parallel groups, three-way blind, randomized, phase 3 on 120 patients. Random Allocation software was used for randomization.

Settings and conduct

Patients are placed in a semi-sitting position (30 degrees), then the supraclavicular block is performed by an ultrasound guide and half of the drug is injected in the pocket corner and the other half in the middle of the brachial plexus. All injections are performed using a spinal needle No. 22 connected to the Extension tube. The drug used for the block is prepared and coded by the project partner as follows and is provided to the executor. The codes are provided to the executor after sampling and statistical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 years and older Weight (Lean body mass) between 50 to 90 kg ASA 1 and 2 were Introduced for upper limb surgery (distal to the lower third of the arm) Exclusion criteria: Local infection at the site of the block Existence of coagulation disorder or taking anticoagulants Hypersensitivity to dexmedetomidine, dexamethasone, and ropivacaine

Intervention groups

In all patients, the supraclavicular block is performed under ultrasound guide by injection of 30 ml of ropivacaine 5 mg/ml by the performer. In the first to third groups, the following items are added in a volume of one ml, respectively: 30 micrograms of dexmedetomidine, 0.6 ml of 7.5% bicarbonate solution, 4 mg (1 ml) of dexamethasone In the control group, 1 ml of normal saline is added to the drug.

Main outcome variables

Interval of drug injection to the onset of sensory and motor block, duration of sensory and motor block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140129016415N9**

Registration date: **2022-06-26, 1401/04/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-26, 1401/04/05**

Update count: **0**

Registration date

2022-06-26, 1401/04/05

Registrant information

Name

Mohammad Golparvar

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Comparative evaluation of effects of adding
Dexmedetomidine, Dexamethasone and Na Bicarbonate
to Ropivacaine in ultrasound-guided supraclavicular
block on the quality of the block in orthopedic surgery

Public title
Evaluation of effects of adding Dexmedetomidine,
Dexamethasone and Na Bicarbonate to Ropivacaine in
ultrasound-guided supraclavicular block

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and older Weight (Lean body mass)
between 50 to 90 kg ASA 1 and 2 Introduced for upper
limb surgery (distal to the lower third of arm)

Exclusion criteria:

Local infection at the site of the block Existence of
coagulation disorder or taking anticoagulants
Hypersensitivity to dexmedetomidine, dexamethasone
and ropivacaine

Age
From 18 years old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: 120

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are placed in one of four experimental groups
using a table of random numbers. The default movement
in the table from right to left and from bottom to top is
considered and the numbers 0 to 29 in group 1 and the
numbers 30 to 59 in group 2 and the numbers 60 to 89
in group 3 and the numbers 90 to 119 They are in group
4. The starting point of the movement in the table is
determined randomly by the first client by placing a
finger with his eyes closed on the table.

Blinding (investigator's opinion)
Double blinded

Blinding description
The project partner prepared the drug used to perform
supraclavicular block by adding additive
(dexmedetomidine, sodium bicarbonate,
dexamethasone, or normal saline) to ropivacaine in

similar syringes and in the same final volume and after
coding (1 to 4) It is provided to the executor, the
executor (drug injector and data collector) and the
patient are not aware of the type of drug added to the
injectable ropivacaine and the codes will be opened after
sampling and statistical analysis are completed.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical
Sciences

Street address

No.100, Jahan-nama valley, Babalrahmeh street,
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Approval date

2022-04-12, 1401/01/23

Ethics committee reference number

IR.MUI.MED.REC.1401.019

Health conditions studied

1

Description of health condition studied

upper limb surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The interval between the injection of the drug and the
onset of anesthesia and immobility

Timepoint

Every 3 minutes

Method of measurement

Evaluation of the movement block is done using 2
movement examinations: 1- Asking the patient to place
the index and middle fingers against each other while
the other fingers are in the extension position 2-
Maintaining the forearm position in a 90 degree position

with the arm in a position The performer places the patient's arm perpendicular to the patient's body. The sensory block is evaluated by pressing the Blunted needle on the three points of the dorsal hand, forearm and arm.

Secondary outcomes

1

Description

Duration of sensory and motor block

Timepoint

Every 15 minutes

Method of measurement

Evaluation of the movement block is done using 2 movement examinations: 1- Asking the patient to place the index and middle fingers against each other while the other fingers are in the extension position 2- Maintaining the forearm position in a 90 degree position with the arm in a position The performer places the patient's arm perpendicular to the patient's body. The sensory block is evaluated by pressing the Blunted needle on the three points of the dorsal hand, forearm and arm.

Intervention groups

1

Description

First intervention group: 30 micrograms of dexmedetomidine in 1 ml of normal saline is added to the 30 ml of ropivacaine used to block.

Category

Treatment - Drugs

2

Description

Second intervention group: 0.6 ml of 7.5% bicarbonate solution is increased to 1 ml with normal saline and then added to Block drug (30 CC ropivacaine)

Category

Treatment - Drugs

3

Description

Third intervention group: 4 mg (1 ml) of dexamethasone is added to the 30 ml of ropivacaine used to block.

Category

Treatment - Drugs

4

Description

Control group: 1 ml of normal saline is added to 30 ml of ropivacaine used to block.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Mohammad Golparvar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mansoor Siavash

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

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Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

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

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