Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Comparison of the effect of dexmedetomidine and fentanyl as adjuvant to lidocaine on the onset time and duration of ultrasound guided infraclavicular brachial plexus block in orthopedic upper limb surgery

Protocol summary

Study aim
To determine the effectiveness of dexmedetomidine and fentanyl as adjuvant to lidocaine on the onset time and duration and postoperative analgesia of ultrasound guided infraclavicular block in orthopedic upper limb surgery

Design
This is a parallel randomized, double- blinded controlled phase 3 clinical trial of 60 patients. A simple randomization method using a table of random numbers is used to generate a random sequence of patients, and individuals are randomly assigned equally to one of the three study groups (20 patients in each group).

Settings and conduct
Patients scheduled for elective upper extremity surgery under infraclavicular block in Akhtar Hospital are enrolled in the study and are randomly divided into three equal groups. Participants, investigators, outcome assessors are not aware of the allocation of study groups.

Participants/Inclusion and exclusion criteria
ASA 1 or 2 patients scheduled for unilateral orthopedic surgery of the elbow or forearm or wrist or hand are included in the study if they give informed consent. Exclusion criteria are ASA class≥3, age more than 75 and less than 15 years, allergy to local anesthetics, coagulation disorders, opium addiction, infection at the block site, BMI>30, uncooperative patients, liver or kidney failure, chronic use of painkillers and narcotics, patients who take narcotics before surgery and pregnancy.

Intervention groups
The control group receives 19 ml of lidocaine 1.5% + 1 ml of normal saline, fentanyl group receives 19 ml of lidocaine 1.5% + 1 ml containing 50 µg of fentanyl and dexmedetomidine group receives 19 ml of lidocaine 1.5% + 1 ml containing 100 µg of dexmedetomidine for infraclavicular block.

Main outcome variables
The onset time of sensory and motor block, the time to achieve complete sensory and motor block, duration of sensory and motor block, degree of sedation, hemodynamic parameters, postoperative analgesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131108015322N7**
Registration date: **2022-10-08, 1401/07/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-08, 1401/07/16**
Update count: **0**

Registration date
2022-10-08, 1401/07/16

Registrant information

Name
Shideh Dabir

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2023-01-10, 1401/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effect of dexmedetomidine and fentanyl as adjuvant to lidocaine on the onset time and duration of ultrasound guided infraclavicular brachial plexus block in orthopedic upper limb surgery

Public title

The effect of adding dexmedetomidine and fentanyl to lidocaine on the the quality of infraclavicular peripheral block in upper extremity orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA class1 and 2 unilateral upper limb surgery age 15-75 years patient's acceptance

Exclusion criteria:

ASA class≥3 Allergy to local anesthetics Age more than 75 yrs and less than 15 yrs Coagulation disorders Opium addiction Infection at the block site BMI >30 liver or kidney failure chronic use of painkillers and narcotics patients who take narcotics before surgery pregnancy

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method by a table of random numbers is used to generate a random sequence of patients and participants are randomly assigned to one of the three study groups. To use the table of random numbers, the researcher first determines the direction of reading the numbers in the table. Then numbers 0-20 are considered for the control group, numbers 21-40 for intervention D group, and numbers 41-60 for intervention F group. Then the researcher puts the hand on one of the numbers and moves in the predetermined direction, records the numbers and assigns them to different groups. Each of the randomly assigned sequence numbers are recorded on a card and each card is placed in a sealed numbered envelope with the same card number. When the eligible participants enter the study, the envelopes are selected in order of their sequence and patients receive the intervention of the same group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and assignment of patients in each group is done by persons with no involvement in the trial. Participants, investigators, care provider and outcome assessors are unaware of the allocation of individuals in each study group.Since the participants, researchers and outcome assessors are unaware of the allocation of the study groups, and the syringes containing the studied drugs are similar in terms of color and volume, this is a double blinded study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of shahid Beheshti University of Medical Sciences

Street address

Building no. 2, 6th floor, Office of Research Affairs, Shahid Chamran Highway, Yemen St., Arabi St., next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences

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Province

Tehran

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1985717443

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.SBMU.MSP.REC.1400.493

Health conditions studied

1

Description of health condition studied

Improving the quality of infraclavicular brachial plexus block in terms of the onset and length of sensory and motor block and analgesic effect

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The onset time of sensory block
Timepoint
After the end of local anesthetic injection every 5 minutes for 20 minutes
Method of measurement
Based on a 0-2 grading scale

2

Description
The onset time of motor block
Timepoint
After the end of local anesthetic injection every 5 minutes for 20 minutes
Method of measurement
Based on modified Bromage scale 0-3

3

Description
Duration of sensory block
Timepoint
After the end of local anesthetic injection every 5 minutes for 20 minutes
Method of measurement
Based on a 0-2 grading scale

4

Description
Duration of motor block
Timepoint
After the end of local anesthetic injection every 5 minutes for 20 minutes
Method of measurement
Based on modified Bromage scale 0-3

Secondary outcomes

1

Description
Heart rate
Timepoint
Before the block, 10, 20, and 30 minutes after the block, 5, 10, and 15 minutes after entering the recovery room, and 3, 12, and 24 hours after operation
Method of measurement
Electrocardiogram, Pulse oximeter

2

Description
Systolic blood pressure
Timepoint
Before the block, 10, 20, and 30 minutes after the block, 5, 10, and 15 minutes after entering the recovery room, and 3, 12, and 24 hours after operation
Method of measurement
Noninvasive Blood pressure measurement method

3

Description
Sedation level
Timepoint
Before the block, 10, 20, and 30 minutes after the block, 5, 10, and 15 minutes after entering the recovery room, and 3, 12, and 24 hours after operation
Method of measurement
Sedation scale with a rating of 1-4

4

Description
Pain severity
Timepoint
10, 20 and 30 minutes after the start of the operation, 5, 10 and 15 minutes after entering the recovery and 3, 12 and 24 hours after operation
Method of measurement
A 5-point verbal rating scale (VRS) consisting of (0 =no pain, 4=unbearable pain)

5

Description
Total number of patient’s requests for systemic analgesics
Timepoint
In the first 24 hours after operation
Method of measurement
Recording the number of requests for analgesic

Intervention groups

1

Description
Control group: Receives 19 ml of lidocaine 1.5% with epinephrine 1:200000 + 1 ml of normal saline for infraclavicular block.
Category
Treatment - Drugs

2

Description
Fentanyl group: Receives 19 ml of lidocaine 1.5% with epinephrine 1:200000 + 1 ml containing 50 µg of fentanyl infraclavicular block.
Category
Treatment - Drugs

3

Description
Dexmedetomidine group: Receives 19 ml of lidocaine 1.5% + 1 ml containing 100 µg of dexmedetomidine for infraclavicular block.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Akhtar hospital

Full name of responsible person
Faramarz Mosaffa

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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shideh Dabir

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable