Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Efficacy comparison between interscalene block with & without superficial cervical block for anesthesia in clavicle surgery

Protocol summary

Study aim
Determining the efficacy of interscalene block without cervical plexus block for anesthesia in clavicle surgery

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 120 patients. Simple randomization will be used in the form of shuffling cards.

Settings and conduct
After the approval of the ethics committee of Shahid Beheshti University of Medical Sciences and obtaining the patient's consent, 120 patients who meet the inclusion criteria will be entered into the study. Patients will be divided by a simple randomization method into one of the groups of interscalene block alone or along with superficial cervical plexus block in the block room of Akhtar Hospital. The people responsible for creating a random sequence from the research team will not be responsible for examining the dependent variable. The data analyst will not know about the coding of the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients weigh less than 80 kg Age between 18 to 60 years Normal neuromotor and sensory function Consent to the operation and performing the anesthetic procedure Non-entry Criteria: Contraindications of nerve blocks (Local infection, coagulopathy, and sensitivity to anesthetics) Persistent treatment or abuse of narcotics, alcohol, or other addictive drugs Mental disorders, restrictive or obstructive pulmonary diseases Pregnancy Consumption of beta-blockers or a heart rate below 50

Intervention groups
Control group: Patients with primary clavicle fracture requiring fixation surgery who undergoing interscalene nerve block and superficial cervical block. Intervention group: Patients with primary clavicle fracture requiring fixation surgery who undergoing interscalene nerve block alone.

Main outcome variables
Need to induce general anesthesia for surgery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230204057318N1**
Registration date: **2023-02-19, 1401/11/30**
Registration timing: **prospective**

Last update: **2023-02-19, 1401/11/30**
Update count: **0**

Registration date
2023-02-19, 1401/11/30

Registrant information
Name
Alireza Shakeri
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-03-21, 1402/01/01
Expected recruitment end date
2023-06-21, 1402/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy comparison between interscalene block with & without superficial cervical block for anesthesia in clavicle surgery

Public title
Interscalene block with & without superficial cervical block

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients weights less than 80 kg Age between 18 to 60 years Normal neuromotor and sensory functions Consent to the operation and performing the anesthetic procedure

Exclusion criteria:
Persistent treatment or abuse of narcotics, alcohol or other addictive drugs Contraindications of nerve blocks (Local infection, coagulopathy and sensitivity to anesthetics) Presence of mental disorders, restrictive or obstructive pulmonary diseases Pregnancy Consuming beta blockers or heart rate below 50

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Creating a random sequence using a simple randomization method using 120 cards (60 cards for each group) that are placed inside opaque sealed envelopes and will be shuffled by the patients before choosing.

Blinding (investigator's opinion)
Double blinded

Blinding description
The people responsible for creating a random sequence from the research team will not be responsible for examining the dependent variable. (The study will be blind.) Also, the data analyst will not know about the coding of the examined groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Yaman st., Shahid Chamran Hwy.

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-01-25, 1401/11/05

Ethics committee reference number
IR.SBMU.MSP.REC.1401.526

Health conditions studied

1

Description of health condition studied
Clavicle fracture surgery

ICD-10 code
S42.0

ICD-10 code description
Fracture of clavicle

Primary outcomes

1

Description
Need to induce general anesthesia for surgery

Timepoint
During surgery

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Postoperative pain score in the recovery room

Timepoint
From the entrance to the recovery room until discharge time from the recovery room

Method of measurement
Visual analogue scale

2

Description

The onset of sensory block

Timepoint

From the end of the nerve block procedure until the beginning of surgery

Method of measurement

Chronometer (Minute)

3

Description

The amount of narcotics used in recovery room

Timepoint

From the entrance to the recovery room until discharge time from the recovery room

Method of measurement

Observation

4

Description

Need for sedation during surgery

Timepoint

During surgery

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: After placing the patient in a suitable position, the interscalene block will be performed by experienced anesthesiologists, all of whom are trained in regional anesthesia. To perform each interscalene block, 20 ml of 1.5% lidocaine (Caspin Co.) along with 1 ml of 8.4% bicarbonate (Caspin Co.) and 1:200,000 epinephrine (Daroupash Co.), plus 4 ml of 0.5% bupivacaine (AstraZeneca Co.) will be used. An ultrasonic guide (S-Nerve Sonosite) with a linear probe of 6-15 MHz will be used to perform the block.

Category

Treatment - Surgery

2

Description

Control group: in the control group, in addition to performing the interscalene block method as described, superficial cervical plexus block with 10 ml of 1.5% lidocaine (Caspin Co.) along with 1 ml of 8.4% bicarbonate (Caspin Co.) and 1:200,000 epinephrine (Daroupakhsh Co.) plus 2 ml of 0.5% bupivacaine (AstraZeneca Co.) will be used. This block will be performed under ultrasonic guidance (S-Nerve Sonosite) with a 6-15 MHz linear probe.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Alireza Shakeri

Street address

Akhtar Hospital, Azar St. Sharifi Avenue, Pole-Romi Avenue, Shariati

City

Tehran

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1964714953

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dr.alirezashakeri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehran, Iran

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1983963113

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zarghi@sbmu.ac.ir

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
Afsaneh Habibi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Yemen Street, Velenjak, Chamran Highway,

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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Medical doctor

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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 more information

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