Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Pain in patients undergoing shoulder surgery using interscalene in comparison with anterior suprascapular nerve block technique

Protocol summary

Study aim
Comparison of postoperative pain control results between intracranial and anterior supraspolar nerve block techniques on postoperative pain in patients undergoing shoulder surgery.

Design
Two groups (30 cases each), 2-3 clinical trials, non-randomized, not blinded

Settings and conduct
Shariati Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria Patients undergoing atherosclerotic shoulder surgery, individuals 21 years and older, body mass index 18-35 kg / m2, complete satisfaction with participation in the study Exclusion criteria Patients who were unable to consent, people who were chronically treated for opioids, people who were allergic to the drug under study, people with neurological defects, people with advanced lung disease (COPD and uncontrolled asthma), high surgeries 3 hours and people who had any contraindications for local anesthesia such as coagulopathy and local infection.

Intervention groups
60 patients will be randomly divided into two groups (ISB, anterior SSNB) based on exclusion criteria.Intracranial nerve blocks (ISBs) (local anesthesia in the area between the C5 and C6 nerve roots, in the gap between the scalps) and the anterior suprascapular (SSNB) (nerves until they detach from the brachial plexus and from under the ohmoid muscle to the supraclavicular cavity Enters) Under the guidance of ultrasound will be performed by a specialist and experienced physician according to the techniques of anesthesia guidelines. Local anesthesia is then applied outside the suprascapular nerve and just below the omoid muscle.

Main outcome variables
side effects, the first time required opioid in 24 hours after surgery, The amount of opioid required in 24 hours after surgery, Pain scoring

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220425054655N1**
Registration date: **2022-06-01, 1401/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-01, 1401/03/11**
Update count: **0**

Registration date
2022-06-01, 1401/03/11

Registrant information

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Rihanna Khorsandi

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
2022-05-22, 1401/03/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Pain in patients undergoing shoulder surgery using interscalene in comparison with anterior suprascapular nerve block technique

Public title
Pain in patients undergoing shoulder surgery using interscalene in comparison with anterior suprascapular nerve block technique

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing atherosclerotic shoulder surgery, People 21 years and older, body mass index 18-35 kg / m2 Complete satisfaction from participating in the study

Exclusion criteria:
Patients who are unable to express satisfaction People who have been chronically treated for opioids People who are allergic to the drugs under study People with neurological defects Patients with advanced lung disease (COPD and uncontrolled asthma) Surgeries over 3 hours People who have any contraindications to local anesthesia such as coagulopathy and local infection

Age
From **21 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Tehran, the intersection of Keshavarz Boulevard and Ghods St., the headquarters of Tehran University of Medical Sciences, sixth floor, Room 605, Research and Technology Affairs Department

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Postal code
1417613151

Approval date
2022-03-16, 1400/12/25

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1508

Health conditions studied

1

Description of health condition studied
Patients undergoing shoulder surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain scoring

Timepoint
16 and 24 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: ISB local anesthesia. Intravenous access is provided and sedation is performed with midazolam (up to 2 mg) and 50 µg fentanyl if necessary. Standard monitors will be used throughout the block and supplemental oxygen will be provided. Intrascal block (ISB) and anterior suprascapular block (SSNB) will be performed under ultrasound guidance. In each group of 15 ml (75 mg) of 0.5% rupivacaine will be used to block. The anterior ISB and SSNB will be performed while the patient is in a supine position. To perform an ISB, an ultrasound scan will be performed to identify the C5, C6, and C7 nerve roots between the scapular muscles. Local anesthesia will be performed in the area between the C5 and C6 nerve roots, in the gap between the scales. Local anesthesia will be performed in the area between the C5 and C6 nerve roots, in the gap between the scales. The success rate of the block in the first 30 minutes after the block will be measured by assessing the degree of sensory and motor block. General anesthesia will be

performed with intravenous fentanyl up to 3 micrograms per kilogram of patient weight, propofol 2 milligrams per kilogram of body weight and atracurium 0.5 mg per kilogram of patient weight. Endotracheal tubes are also implanted for patients. Fentanyl will be used in the recovery room if necessary and its amount will be recorded. Pain will be measured by the VAS scale 16 and 24 hours after recovery recovery. The first request for analgesia, the need for analgesia in the first 24 hours after the block, patient satisfaction, and side effects will also be considered. The total number of additional analgesic prescriptions for 48 hours after surgery will also be calculated.

Category

N/A

2

Description

Intervention group: SSNB local anesthesia. Intravenous access is provided and sedation is performed with midazolam (up to 2 mg) and 50 µg fentanyl if necessary. Standard monitors will be used throughout the block and supplemental oxygen will be provided. Intrascal block (ISB) and anterior suprascapular block (SSNB) will be performed under ultrasound guidance. In each group of 15 ml (75 mg) of 0.5% rupivacaine will be used to block. The anterior ISB and SSNB will be performed while the patient is in a supine position. For the anterior SSNB, the nerve will follow until it separates from the brachial plexus and enters the supraclavicular cavity below the ohmoid muscle. Local anesthesia will then be applied outside the suprascapular nerve and just below the omoid muscle. The success rate of the block in the first 30 minutes after the block will be measured by assessing the degree of sensory and motor block. General anesthesia will be performed with intravenous fentanyl up to 3 micrograms per kilogram of patient weight, propofol 2 milligrams per kilogram of body weight and atracurium 0.5 mg per kilogram of patient weight. Endotracheal tubes are also implanted for patients. Fentanyl will be used in the recovery room if necessary and its amount will be recorded. Pain will be measured by the VAS scale 16 and 24 hours after recovery recovery. The first request for analgesia, the need for analgesia in the first 24 hours after the block, patient satisfaction, and side effects will also be considered. The total number of additional analgesic prescriptions for 48 hours after surgery will also be calculated.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان شریعتی

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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?

No

Title of funding source

Vice-Chancellor in Research Affairs of Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Reza Atefyekta

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The use of data and documents is permitted in accordance with what will be extracted from the article.

From where data/document is obtainable
Reza AtefYekta

What processes are involved for a request to access data/document
Six months after the publication of the article, the application will be reviewed by the project manager and submitted as soon as possible.

Comments