# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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**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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**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**

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## Sponsors / Funding sources

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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**

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Tehran University of Medical Sciences

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**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**