Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Effect of Interscalene Nerve Block on Pain Control After Rotator Cuff Repair Surgery in the First Two Weeks-Interventional - Randomized controlled clinical trial

Protocol summary

Study aim

Effect of Interscalene Nerve Block on Pain Control After Rotator Cuff Repair Surgery in the First Two Weeks-Interventional - Randomized controlled clinical trial

Design

The current study is a single-blind clinical trial study that will be conducted in parallel. A total of 156 patients who are Candidate for open rotator cuff repair surgery patients will be included in the study. Eligible patients are randomly divided into two equal groups of A and B.

Settings and conduct

Patients who are Candidate for open rotator cuff repair surgery who visit Ghadir Mother and Child Hospital in Shiraz during the study will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using the random block method. This study will be conducted in a single-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with ASA grade I or II, patients between 18 and 65 years old, Candidate for open rotator cuff repair surgery and Tendon retraction measuring 2 centimeters or more. Exclusion criteria: allergy to the drugs used in the study, history of heart, respiratory, kidney diseases and addiction and pregnancy.

Intervention groups

Intervention Group: Patients in this group will receive an interscalene nerve block performed by an anesthesiologist prior to surgery. The block will be administered at the C6 vertebral level, targeting the anterior and middle scalene muscles under ultrasound guidance. A total of 20 mL of 0.5% bupivacaine will be injected. In addition to the nerve block, patients will receive 600 mg oral Gabapentin for two weeks postoperatively. anesthesia induction will be performed uniformly for all patients. Control Group: Patients in this group will receive 600 mg oral Gabapentin for two weeks, Anesthesia induction will be conducted identically to that of the intervention group.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091117002723N6**
Registration date: **2025-06-20, 1404/03/30**
Registration timing: **prospective**

Last update: **2025-06-20, 1404/03/30**
Update count: **0**

Registration date

2025-06-20, 1404/03/30

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

07112337636

Email address

hadavimr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-01, 1404/07/09

Expected recruitment end date

2026-05-01, 1405/02/11

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Interscalene Nerve Block on Pain Control After Rotator Cuff Repair Surgery in the First Two Weeks-Interventional - Randomized controlled clinical trial

Public title
Effect of Local Anesthetic Injection Near Shoulder Nerves on Pain Reduction for Cuff Repair Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients with ASA grade I or II (American Society of Anesthesiology classification) Patients between 18 and 65 years old Patients candidates for open rotator cuff repair surgery Tendon retraction measuring 2 centimeters or more Consent to participate in the study
Exclusion criteria:
Allergy to the drugs used in the study Positive history of Heart, respiratory, kidney diseases and addiction Pregnancy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **156**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups using block randomization. In this method, blocks of sizes 4, 6, and 8 are generated, each containing an equal number of patients allocated to groups A and B in alternating permutations. Patients are then randomly and equally distributed into the two groups based on these permuted blocks. The block sequences will be generated using the website www.sealedenvelope.com.
Blinding (investigator's opinion)
Single blinded
Blinding description
In the operating room, The pain service anesthesiologist will perform only the nerve block and general anesthesia, while another independent anesthesiologist, blinded to randomization and anesthesia results, will only review and record the study variables. This study is single-blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz Medical School
Street address
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2025-05-21, 1404/02/31
Ethics committee reference number
IR.SUMS.MED.REC.1404.137

Health conditions studied

1

Description of health condition studied
Rotator cuff tear
ICD-10 code
M75.1
ICD-10 code description
Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes

1

Description
Pain
Timepoint
The pain score is recorded at 6 hours, 12 hours, 24 hours, 48 hours, 1 week, 10 days, and 2 weeks after surgery.
Method of measurement
Questionnaire and Numerical Pain Rating Scale (NRS)

Secondary outcomes

empty

Intervention groups

1

Description
Group 1(Intervention Group): Patients in this group will receive an interscalene nerve block performed by an anesthesiologist prior to surgery. The block will be administered at the C6 vertebral level, targeting the

anterior and middle scalene muscles under ultrasound guidance. A total of 20 mL of 0.5% bupivacaine will be injected. The correct placement of the block will be confirmed by eliciting a brief contraction of the deltoid muscle using a nerve stimulator. In addition to the nerve block, patients will receive 600 mg oral Gabapentin for two weeks postoperatively. Upon arrival in the operating room, all patients will undergo comprehensive monitoring including pulse oximetry, electrocardiogram, and non-invasive blood pressure measurement. Following the nerve block, anesthesia induction will be performed uniformly for all patients.

Category

Treatment - Drugs

2

Description

Group 2(Control Group): Patients in this group will receive 600 mg oral Gabapentin for two weeks postoperatively without undergoing the interscalene nerve block. Similar to the intervention group, these patients will be monitored upon arrival in the operating room with pulse oximetry, electrocardiogram, and non-invasive blood pressure monitoring. Anesthesia induction will be conducted identically to that of the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother and Child Hospital

Full name of responsible person

Seyed Ali Hadavi

Street address

Ghadir Mother and Child Hospital, the beginning of Golshan town, above the Quran gate.

City

Shiraz

Province

Fars

Postal code

۷۱۴۴۹۹۵۳۷۷

Phone

+98 71 3227 9701

Fax

Email

Motherhosp@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

Street address

7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3235 7282

Email

mohammadi@sums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Ali Hadavi

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street.

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

sahadavi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Seyed Mohammad Reza Hadavi

Position
Assistant Professor of Pain Anesthesiology

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Anesthesiology Department, Faghihi Hospital, Zand Street.

City
Shiraz

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7134844119

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+98 71 3647 4270

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hadavimr@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamide Saeedizade

Position
Research Assistant

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

Street address
Anesthesiology Department, Faghihi Hospital, Zand Street

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Postal code
7134844119

Phone
0098-36281460

Email
saeedi.hamide@gmail.com

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