

# 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](http://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

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3647 4270

**Email**

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

**City**

Shiraz

**Province**

Fars

**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