# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Oct 2026

## Comparison of the effects of intravenous dexmedetomidine and the local perineural combination of dexmedetomidine and ropivacaine on the duration of interscalene block and hemodynamic parameters in patients undergoing shoulder surgery

## Protocol summary

**Study aim**

Comparison of the effects of intravenous dexmedetomidine and the local perineural combination of dexmedetomidine and ropivacaine on the duration of interscalene block and hemodynamic parameters in patients undergoing shoulder surgery

**Design**

The clinical trial study is single-blinded and randomized. After the patients are assigned to the study groups, all patients are similarly went under general anesthesia. At the end of the procedure and before the patient is reversed, an interscalene block is performed according to the defined pattern. To perform the interscalene block, a 5 cm needle No. 22 (B. Brown Medical Company, USA) is inserted under ultrasound guidance in an out-of-plane approach and advanced until the needle tip is adjacent to the C5 and C6 roots. The prepared drug is injected at this location.

**Settings and conduct**

The study will be conducted at Shariati and Imam Khomeini Hospitals of Tehran University of Medical Sciences. The study is single-blinded and blinding is only in patients who are unaware of the perineurally injected substance.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patients age between 18 to 75 years old Patients undergoing elective shoulder surgery Patients with ASA class one and two Exclusion criteria: Known Allergy to local anesthetic drugs Presence any kinds of neurologic, vascular and neuromuscular diseases Presence of hematologic and coagulation abnormalities Chronic opioid usage

**Intervention groups**

First intervention group: dexmedetomidine injection 0.5mcg/kg with 30cc of ropivacaine 0.5% perineural Second intervention group: intravenous dexmedetomidine injection 0.5mcg/kg with 30cc of ropivacaine 0.5% perineural Control group: ropivacaine 0.5% perineural injection

**Main outcome variables**

After the intervention, patients are evaluated for the success of the motor block and hemodynamic changes.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20231130060227N1**
Registration date: **2025-10-23, 1404/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-23, 1404/08/01**
Update count: **0**

**Registration date**

2025-10-23, 1404/08/01

**Registrant information**

**Name**
Keyvan Teymourei khanesari
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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keyvan.teymourei1990@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-09-23, 1404/07/01

**Expected recruitment end date**

2026-03-11, 1404/12/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effects of intravenous dexmedetomidine and the local perineural combination of dexmedetomidine and ropivacaine on the duration of interscalene block and hemodynamic parameters in patients undergoing shoulder surgery

**Public title**

Comparison of the effects of intravenous dexmedetomidine and the local perineural combination of dexmedetomidine and ropivacaine on the duration of interscalene block and hemodynamic parameters in patients undergoing shoulder surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients age between 18 to 75 years old Patients undergoing elective shoulder surgery Patients with ASA class one and two

**Exclusion criteria:**

Known Allergy to local anesthetic drugs Presence any kinds of neurologic, vascular and neuromuscular diseases Presence of hematologic and coagulation abnormalities Chronic opioid usage (more than six months)

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided equally into 2 groups using the Block Randomization method. In this way, the treatment order was determined from the different states of the 4-blocks (AABB, ABAB, BBAA, BABA, BAAB, ABBA) randomly using a random number table and the placement of the 4-blocks in each list in such a way that there are no structural differences in the medical and demographic records of the patients in the groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients participating in the study are informed about the drug injection during the interscalene block, and these patients are blinded to the type of drug injected during the interscalene block. The researcher is fully aware of the type of substance injected into each patient and is not blinded.

**Placebo**

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**

Shariati Educational, Research and Treatment Center, opposite the Faculty of Economics, Jalal Al-Ahmad Intersection, North Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Approval date**

2017-10-29, 1396/08/07

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1396.3804

## Health conditions studied

### 1

**Description of health condition studied**

Study on the rate of motor block and postoperative pain in patients undergoing shoulder surgery.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Duration of Interscalen block

**Timepoint**

The duration of sensory block is determined from the onset of the block (confirmed by pinprick testing) until the return of sensation. The duration of motor block is determined from the onset of the block (confirmed by loss of muscle force) until the return of full force.

**Method of measurement**

The variables are based on sensory clinical examination

(pinprick test) and motor clinical examination (muscle force test).

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
First Intervention group: Received dexmedetomidine 5mcg/kg with 30cc ropivacaine 0.5% perineural
**Category**
Treatment - Drugs

### 2

**Description**
Second Intervention group: Received dexmedetomidine 5mcg/kg intravenously with 30cc ropivacaine 0.5% perineural
**Category**
Treatment - Drugs

### 3

**Description**
Control group: Received 30cc ropivacaine 0.5% perineural
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shariati hospital
**Full name of responsible person**
Mahshid Karimi
**Street address**
Shariati Educational, Research and Treatment Center, opposite the Faculty of Economics, Jalal Al-Ahmad Intersection, North Kargar Street, Tehran
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Ramin Kordi
**Street address**
Tehran university of medical sciences, faculty of medicine, Poursina Avenue, Quds Avenue, Enghelab Boulevard
**City**
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tumspr@tums.ac.ir
**Web page address**
https://medicine.tums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
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**
Hamed Abdollahi
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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Keyvan Teymourei khanesari
**Position**
Anesthesiologist
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1411713135
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keyvan.teymourei1990@gmail.com

## 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**
Yes - There is a plan to make this available
**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**
Study data can be shared after being de-identified.
**When the data will become available and for how long**
Use of study data will be available for at least one year after publication of study results.
**To whom data/document is available**
All anesthesiologists and pain specialists will have access to the data.
**Under which criteria data/document could be used**
Data analysis and use of results by orthopedic specialists will also be available.
**From where data/document is obtainable**
To access the database, please contact the person responsible for the study, Dr. Hamed Abdollahi.
**What processes are involved for a request to access data/document**
The documents and data will be accessible according to the specified timeframe and upon formal request from academic and non-academic research centers.
**Comments**