Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 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)

Phone
+98 21 2294 7046

Email address
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
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
shariatihosp@tums.ac.ir
Web page address
https://shariati.tums.ac.ir

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
Tehran
Province
Tehran
Postal code
1461884513
Phone
+98 21 8895 3003
Email
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
Street address
Faculty of medicine, Poursina Avenue, Quds Avenue, Enghelab boulevard
City
Tehran

Province
Tehran
Postal code
1461884513
Phone
+98 21 6672 7060
Email
hamiralam@sina.tums.ac.ir

Person responsible for scientific 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
Street address
Faculty of medicine, Poursina Avenue, Quds Avenue, Enghelab boulevard
City
Tehran
Province
Tehran
Postal code
1461884513
Phone
+98 21 6672 7060
Email
hamiralam@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Keyvan Teymourei khanesari
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology department, First floor, Shariati hospital, North Kargar street
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 2294 7046
Fax
Email
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