Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

To Asses the Effects of Adding Dexmedetomidine to Ropivacaine in Interscalen Block with Ultrasound Guide prior to Arthroscopically Repairing the Ruptured Shoulder Tendon Surgery in need of Amount of Anesthetic Drugs during Surgery and Post Operation Analgesia.

Protocol summary

Study aim
To asses the effects of adding Dexmedetomidine to Rupivacaine in interscallen block with ultrasound guide prior to arthroscopically repairing the ruptured shoulder tendon surgery in need of anesthetic drugs during surgery and analgesia after surgery

Design
A clinical trial with parallel, double-blind, phase 2 was performed on 42 patients.

Settings and conduct
Rasool Akram Hospital in Tehran

Participants/Inclusion and exclusion criteria
42 patients undergoing arthroscopic surgery to repair rotator cuff shoulder rupture

Intervention groups
Group 1: receive 20 cc of Rupivacaine 0.25% plus 2 cc of normal saline under the interscallen block of the brachial plexus with ultrasound guide. Group 2: receive 20 cc of Ropivacaine 0.25% plus 1.5 µ / kg dexmethomidine under interscallen block of brachial plexus with ultrasound guide.

Main outcome variables
The addition of Dexmedetomidine to Ropivacaine in the interscallen block increases the duration of analgesia after shoulder surgery. The addition of Dexmedetomidine to Ropivacaine in the interscallen block reduces the need for anesthetic drugs during shoulder surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181011041308N4**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **prospective**
Last update: **2021-12-11, 1400/09/20**
Update count: **0**

Registration date
2021-12-11, 1400/09/20

Registrant information

Name
Mahmoud Reza Alebouyeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2213 6136

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alebuieh.mr@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-07-23, 1401/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To Asses the Effects of Adding Dexmedetomidine to Ropivacaine in Interscalen Block with Ultrasound Guide prior to Arthroscopically Repairing the Ruptured Shoulder Tendon Surgery in need of Amount of Anesthetic Drugs during Surgery and Post Operation Analgesia.

Public title

To asses the effects of adding Dexmedetomidine to Ropivacaine in interscallen block.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are satisfied with their participation in the research project. Patients undergoing elective surgery. Patients aged between 18 and 60 years.

Exclusion criteria:

Pregnant patients. Patients with ASA 4 and ASA 5. Patients with asthma and copd BMI>35 Opioid addiction and use of NSAID or opium in last 3-5 days before Diabetic patients. Patients with coagulopathy disorder any AV Block changes in the ECG. Head Trauma Any Abnormality in arm and forearm Any contraindications of interscalen block such as diaphragmatic paralysis in the other side

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants were blinded by a clinical observer, caregiver, and outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-06-23, 1399/04/03

Ethics committee reference number

IR.IUMS.FMD.REC.1399.223

Health conditions studied

1

Description of health condition studied

Rupture of shoulder rotator cuff

ICD-10 code

M75.1

ICD-10 code description

Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes

1

Description

1- Investigating the difference between NRS in the hours after surgery in the two groups

Timepoint

during the surgery ,2 hours, 6 hours, 18 hours and 24 hours after surgery

Method of measurement

Anesthetic recording papers,Bispectral index monitoring,ask patients

2

Description

Frequency of using the Autofuser pump in the two groups -The first hour of using the Autofuser pump in the two groups - The amount of pethidine consumption in the two groups - The first hour of using the pethidine in the two groups -Propofol consumption in both groups - Atracurium consumption in two groups - Remifentanil consumption in both groups

Timepoint

during the surgery ,2 hours, 6 hours, 18 hours and 24 hours after surgery

Method of measurement

Anesthetic recording papers,Bispectral index monitoring,ask patients

Secondary outcomes

1

Description

range of motion and frozen shoulder after 3 months and 6 months of surgery

Timepoint

3months and 6 months after surgery

Method of measurement

physical examination

Intervention groups

1

Description
Intervention group: The first group receives 20 cc of Rupivacaine 0.25% plus 2 cc of normal saline under the interscallen block of the brachial plexus with ultrasound guide. .
Category
Treatment - Drugs

2

Description
Intervention group: The second group receives 20 cc of Rupivacaine 0.25% plus 1.5 µ / kg dexmethomidine under interscallen block of the brachial plexus with ultrasound guide
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Shirin Zarandooz
Street address
Niyayesh St
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1445613131
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Abdolreza Pazouki
Street address
Tehran Hemat Highway next to Milad Tower
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1449614535
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Shirin Zarandouz
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Only part of the data containing information about the main outcome can be shared.
When the data will become available and for how long
Access period starts 3 months after the results are published.
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
It is necessary to send a request for access to data or documents.
From where data/document is obtainable
Refer to Dr. Mahmoud Reza Alebouyeh. Phone: 00989121253698
What processes are involved for a request to access data/document
After submitting the request, if approved by the committee and during the legal process, the documents will be sent.
Comments