

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 interscalen 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 interscalen block of the brachial plexus with ultrasound guide. Group 2: receive 20 cc of Ropivacaine 0.25% plus 1.5 µ / kg dexmethomidine under interscalen block of brachial plexus with ultrasound guide.

Main outcome variables

The addition of Dexmedetomidine to Ropivacaine in the interscalen block increases the duration of analgesia after shoulder surgery. The addition of Dexmedetomidine to Ropivacaine in the interscalen 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)

Phone

+98 21 2213 6136

Email address

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 assess the effects of adding Dexmedetomidine to Ropivacaine in interscalen 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 interscalen 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 interscalen 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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shirin_zarandouz@yahoo.com

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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PR@iums.ac.ir

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 scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahmoud Reza Alebouyeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Fax**Email**

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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