

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of Bupivacaine and dexmedetomidine with Bupivacaine local injection alone on postoperative functional and pain in patient under shoulder rotator cuff repair with general anesthesia

Protocol summary

Study aim

The purpose of this study will be to assess the effects of Bupivacaine and dexmedetomidine with Bupivacaine local injection alone on postoperative functional and pain in patient under shoulder rotator cuff repair with general anesthesia

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 3-2.

Settings and conduct

In Urmia Imam Khomeini hospital operating room the patients needing to repair elective rotator cuffs will be divided into two parallel groups (30 patients per group). Patients in the first group will be treated with topical injection of bupivacaine at the end of surgery (0.1% diluted with normal saline 10 cc) and in the other group with the same volume of drug plus 1 microgram per kg body weight of the intra-articular and extra-articular dexmedetomidine and will be compared with each other. Each of the medicines will be provided by an anesthetic technician in 10 ml syringes of the same type and neither anesthetist nor orthopedic specialist will be informed of its content.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 20 to 70 years, American Society of Anesthesiologists physical status classification I and II, Absence of extensive damage to the rotator cuff
Exclusion criteria: History of allergy to used drugs, The history of drug addiction, Known coagulation disorders, History of renal disease, History of liver disease, Body mass index more than 35 kg/m²

Intervention groups

In intervention group bupivacaine 0.1 % (diluted with normal saline 10 cc) plus 1 microgram per kg body weight in site of surgery will be injected topically In control group topical injection bupivacaine 0.1 % (

diluted with normal saline 10 cc) in site of surgery will be injected topically.

Main outcome variables

pain, function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N16**

Registration date: **2019-07-13, 1398/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Bupivacaine and dexmedetomidine with Bupivacaine local injection alone on postoperative functional and pain in patient under shoulder rotator cuff repair with general anesthesia

Public title

Evaluation the effects of Bupivacaine and dexmedetomidine on postoperative functional and pain

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

aged 20 to 70 years American Society of Anesthesiologists physical status classification I and II
Absence of extensive damage to the rotator cuff

Exclusion criteria:

History of allergy to used drugs The history of drug addiction Known coagulation disorders History of renal disease History of liver disease Body mass index more than 35 kg/m²

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups of Dexmedetomidine and Bupivacaine (group D) and Bupivacaine (group B) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist will be unaware of which patient will be assigned to which group. Syringes will be identical and only the operating room nurse will know about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-12-26, 1397/10/05

Ethics committee reference number

IR.UMSU.REC.1397.388

Health conditions studied**1****Description of health condition studied**

pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes**1****Description**

pain

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

2**Description**

function

Timepoint

On the day before surgery and on postoperative day

Method of measurement

QoR-40 scoring system

Secondary outcomes

1

Description

Mean Arterial Blood Pressure

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

None Invasive Blood Pressure

2

Description

Mean pulse Rate

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Electrocardiogram

3

Description

sleep disturbance

Timepoint

Until 24 hours after surgery

Method of measurement

Ten point scale

Intervention groups

1

Description

Intervention group: topical injection bupivacaine 0.1 % (diluted with normal saline 10 cc) plus dexmedetomidine 1 microgram per kg body in site of surgery

Category

Prevention

2

Description

Control group: topical injection bupivacaine 0.1 % (diluted with normal saline 10 cc) in site of surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital, C operating room

Full name of responsible person

Shahryar Sane

Street address

Modarres Boulevard, Ershad Boulevard

City

Uemia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3346 9931

Fax

+98 44 3346 8967

Email

sanesh@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3223 4897

Email

research@umsu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

sanesh@umsu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

sanesh@umsu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

sanesh@umsu.ac.ir

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

Not applicable

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