Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 devided 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 weightin 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, functoin

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 knew 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 commitee 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