Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Interscalen brachial plexus blockade combined with Perineural dexamethasone for post operative analgesia after shoulder surgery

Protocol summary

Study aim

Investigating the effect of perineural dexamethasone combination in brachial plexus interscalene block in shoulder surgery on postoperative pain

Design

During this RCT, the number of 60 patients candidates for shoulder surgery are allocated randomly into 2 groups of 30 patients according to Including and excluding criteria. In the control group, lidocaine 2 cc (1.5%) , bupivacaine 20 mg (2cc, 0.5%) , and 2 cc normal saline are used for interscalene block. In the case group, lidocaine 2 cc (1.5%) , 2cc bupivacaine 0.5% (20mg), and 2cc dexamethasone (8mg) are used. VAS score is used to measure pain 12 hours and 24 hours after the operation

Settings and conduct

During this RCT, the number of 60 patients candidates for shoulder surgery are allocated randomly into 2 groups of 30 patients according to Including and excluding criteria. In the control group, lidocaine 2 cc (1.5%) , bupivacaine 20 mg (2cc, 0.5%) , and 2 cc normal saline are used for interscalene block. In the case group, lidocaine 2 cc (1.5%) , 2cc bupivacaine 0.5% (20mg), and 2cc dexamethasone (8mg) are used. VAS score is used to measure pain 12 hours and 24 hours after the operation This research is double-blind and the physician injecting the drugs and the physician performing the post-operative evaluations are different and do not know about the content of the syringes and the cases.

Participants/Inclusion and exclusion criteria

Patients with ASA class I and II candidates for shoulder surgery referred to Shohadaye Tajrish and Akhtar Hospitals affiliated to Shahid Beheshti University of Medical Sciences.

Intervention groups

In the control group, 30 cc lidocaine1.5%, 2cc bupivacaine 0.5%(20mg), and 2cc of normal saline are injected between the C5-C6 roots of spine. In the case group, 30cc lidocaine 1.5%, 2 cc bupivacaine 0.5%(20 mg), 2cc of dexamethasone 8mg is injected between the same roots

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170423033615N3**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **retrospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Mahshid Ghasemi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2226 5454

Email address

mahshidghasemi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Interscalen brachial plexus blockade combined with Perineural dexamethasone for post operative analgesia after shoulder surgery

Public title

Interscalen brachial plexus blockade combined with Perineural dexamethasone for post operative analgesia after shoulder surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I , ASA II Candidate for shoulder surgery No substance abuse in the past 6 weeks No orthopedic surgery in the lower limb under spinal anesthesia no respiratory diseases, diabetes; Cardiovascular no drug addiction according to definition Normal body temperature No history of shivering No history of seizures Absence of tremors or Parkinson's Not taking NSAIDs 24 hours before surgery Absence of infection or wound No Allergy to local anesthetics Not pregnant and breastfeeding Duration of surgery maximum 3 hours No allergy to Estroids

Exclusion criteria:

History of psychiatric disorders patient refusal or inability to give informed consent ASA class III and above anticoagulants History of adverse reactions to steroids History of adverse reactions to local anesthetics History of drug abuse Occurrence of complications that require intervention within 24 hours after the operation receiving blood transfusion during surgery or anesthesia central body temperature to less than 32 degrees Celsius during surgery

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, based on the table of random numbers, first the number of samples is entered using a computer, and for each patient two-digit code is assigned . The researcher randomly selects a point in the Weston line. If the number is smaller than the sample size, the selection is made. And this continues until the sample size is complete

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, the drugs of the case group and the control group are drawn into the syringe by the nurse anesthetist. Therefore, the nurse is aware of the types of drugs of the two groups. The researcher, who is an anesthesiologist, does not know which group the drug belongs to. So the researcher is blind at this stage. On the other hand, the participants of the study are also blind to the difference of drugs in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research and Technology of Shahid Beheshti University Of Medical Sciences

Street address

Shahid Abbas Arabi Street, Shahid Beheshti University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-02-12, 1401/11/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.754

Health conditions studied

1

Description of health condition studied

post operation pain in shoulder surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

12 hours after the operation, 24 hours after the

operation

Method of measurement

VAS Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group,the combination of lidocaine 1.5% in the amount of 2 cc, bupivacaine 0.5% in the amount of 2 cc (20 mg), and 2 cc of dexamethasone (8 mg) are injected between the roots of C5-C6 cervical spine.

Category

Treatment - Surgery

2

Description

Control group: the combination of 30 cc lidocaine1.5%, 2cc bupivacaine 0.5%(20mg), and 2cc of normal saline are injected between the C5-C6 roots of spine

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Faranak Behnaz MD

Street address

Shahrdari Str, Tajrish Sqr,

City

Tehran

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19899 34148

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+98 912 203 9978

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faranak_behnaz@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Mahshid Ghasemi MD

Street address

Sharifi Manesh Str, Shariati Ave

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1964714953

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mahshidghasemi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology of Shahid Beheshti University Of Medical Sciences

Street address

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1985717434

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mpd@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahshid Ghasemi MD

Position

Associate professor in Anesthesia, Pain medicinefellowship

Latest degree

Subspecialist

Other areas of specialty/work
Fellowship in Pain medicine

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Pain Clinic, Akhtar Hospital, Shariati str, Sharifi Manesh Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Person responsible for updating data

Contact

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Position
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Email
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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
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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Information on the initial implications

When the data will become available and for how long
since 2023

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
There are no special conditions

From where data/document is obtainable
Mahshid Ghasemi MD, mahshidghasemi@sbmu.ac.ir

What processes are involved for a request to access data/document
Send a request by e-mail

Comments