# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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,

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### 2

**Recruitment center**

**Name of recruitment center**

Akhtar Hospital

**Full name of responsible person**

Mahshid Ghasemi MD

**Street address**

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## 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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**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

**Street address**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Name of organization / entity**
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
Mahshid Ghasemi MD

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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**