

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of Volume of Bupivacaine on Postoperative Pain After Shoulder Surgery Under Interscalene Block of Brachial Plexus

Protocol summary

Summary

In current prospective randomized double-blinded clinical trial, 20 patients aged between 20 to 65 years old candidate for shoulder surgery, with grade I or II of American society of anesthesiology (ASA), will be enrolled. Patients with psychotic disorders, obstructive pulmonary diseases and body mass index greater than 30 kg/m², will be excluded. Anesthesia induction will be similar in all patients, using 0.03 mg/kg midazolam, 1-2 microgram/kg fentanyl, 2 mg/kg propofol and 0.15 mg/kg cisatracurium. At the end of the operation and subsequent to supine positioning of the patients interscalene block will be administered in both study groups via classic Winnie method. Injection spot will be determined by nerve stimulation and ultrasonography guidance. Subsequent to randomized allocation of patients to study groups, Interscalene block performed by 15 ml of 0.5% bupivacaine in the first group and by 30 ml of 0.25% bupivacaine in the second group. Pain severity measurement performed using quadruple pain scale (including no pain, mild pain, moderate pain and severe pain) in the recovery room and after discharge from recovery room measured by Visual Analogue Scale (VAS). Duration of analgesia considered as first requisition of patient to receive analgesics. Patients will be blinded to received bupivacaine dosage and anesthesiologist that records data will be blinded to patients study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050733848N1**

Registration date: **2017-05-25, 1396/03/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-25, 1396/03/04

Registrant information

Name

Taghi Abedini

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3334 1994

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Volume of Bupivacaine on Postoperative Pain After Shoulder Surgery Under Interscalene Block of Brachial Plexus

Public title

Bupivacaine effect on analgesia subsequent to brachial plexus block

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients aged between 20 to 65 years old candidate for shoulder surgery; Class I or II according to ASA classification. Exclusion criteria: consumption of anti-psychotic drugs; drug abusers; history of psychotic disorders; obstructive pulmonary diseases; body mass index greater than 30 kg/m²; emergent operations; change in anesthesia or surgery procedure due to severe complications.

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz university of medical sciences, Daneshgah square

City
Tabriz

Postal code

Approval date
2017-03-06, 1395/12/16

Ethics committee reference number
IR.TBZMED.REC.1395.1323

Health conditions studied

1

Description of health condition studied
Shoulder injuries

ICD-10 code

S40-S49

ICD-10 code description

Injuries to the shoulder and upper arm

Primary outcomes

1

Description

Patients pain severity after shoulder surgery during recovery

Timepoint

Postoperative recovery

Method of measurement

quadruple pain severity scale

2

Description

Patients pain severity after shoulder surgery during recovery

Timepoint

6 hours, 12 hours and 24 hours after surgery

Method of measurement

Using visual analogue scale

3

Description

duration of analgesia after shoulder surgery

Timepoint

Postoperative period

Method of measurement

Questionnaire

Secondary outcomes

1

Description

postoperative complications hypotension

Timepoint

postoperative admission period

Method of measurement

Questionnaire

2

Description

postoperative nausea and vomiting

Timepoint

during admission

Method of measurement

Questionnaire

Intervention groups

1

Description

Control group: interscalen block will be applied by low

dose bupivacaine including 15 ml of 0.5% bupivacaine solution.

Category

Treatment - Drugs

2

Description

Study group: interscalen block will be applied by low dose bupivacaine including 30 ml of 0.25% bupivacaine solution.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Dr. Masoud Parish

Street address

Shohada hospital, Golshahr street, Yaxchian, Tabriz, Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of medical sciences, Daneshgah square

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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Masoud Parish

Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor, Specialist in anesthesiology

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty