

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effects of low dose interscalene block in addition to general anesthesia on recovery parameters from anesthesia in shoulder surgery

Protocol summary

Summary

Excellent postoperative pain control plays central role in the outcome of open shoulder surgery which provides early rehabilitation and accelerates functional recuperation. Interscalen Brachial Plexus Block is one of the most common performed block for upper limb surgery which has low incidence of complication and can be performed easily by anesthesiologists. In this study we evaluate the effect of low dose interscalen brachial plexus block on recovery parameters of patients undergoing shoulder surgery. Fifty patients who are candidate for elective shoulder surgery will be enrolled in this study. Inclusion criteria is every adult patient who candidate for elective shoulder surgery and can tolerate a 25% decrease in lung capacities (Forced vital capacity) and exclusion criteria are infection in site of block, coagulopathy, neuropathy, history of damage to brachial plexus and allergy to local anesthetic. Patients will be randomized to two 25-patient groups. One group will receive morphin sulfate and in the other group small volume Interscalene Brachial Plexus Block (ISBPB) will be performed. Pain severity, patient satisfaction scores and post anesthesia recovery parameters (agitation, Post Anesthetic Care Unit length of stay, eyes opening and reply to verbal stimulation) will be assessed. Primary outcome is recovery parameters like pain, patient satisfaction, agitation, eyes opening, reply to verbal stimuli and secondary outcome is discharge from PACU (Post Anesthetic Care Unit).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011072582N2**

Registration date: **2010-12-25, 1389/10/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-25, 1389/10/04

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-10-20, 1389/07/28

Expected recruitment end date

2011-10-20, 1390/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of low dose interscalene block in addition to general anesthesia on recovery parameters from anesthesia in shoulder surgery

Public title

Efficacy of Interscalen block in shoulder surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: every adult patient who are candidate for elective shoulder surgery and can tolerate a 25% decrease in lung capacities (Forced vital capacity).

Exclusion criteria: infection in site of block, coagulopathy, neuropathy, history of damage to brachial plexus and allergy to local anesthetic.

Age

From **18 years** old to **81 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2009-05-20, 1388/02/30

Ethics committee reference number

88/1-4/3

Health conditions studied

1

Description of health condition studied

post operative pain

ICD-10 code

Y84

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without

mention of misadventure at the time of the procedure

2

Description of health condition studied

post operative pain

ICD-10 code

Y83

ICD-10 code description

Surgical operation and other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

recovery parameters

Timepoint

During PACU (post anesthetic care unit) stay

Method of measurement

Visual analogue scale for pain, Two point score for patient satisfaction, Ramsey score for agitation, eyes opening by verbal stimuli

Secondary outcomes

1

Description

patient discharge

Timepoint

duration of post anesthetic care unit

Method of measurement

hours of PACU stay

Intervention groups

1

Description

Intervention; general anesthesia plus low dose interscalen block with 20 ml of lidocaine 1.5%

Category

Treatment - Other

2

Description

Control: only General anesthesia same as the intervention group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
General ICU of Shohada hospital
Full name of responsible person
Ata Mahmoodpoor
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostad Rahimi
Street address
Faculty of Health and Nutrition
City
Tabriz
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
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Person responsible for updating data

Contact

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