

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the success rate of intracranial and supraclavicular combined block of the brachial plexus under ultrasound guide compared to single intracclanic and supraclavicular block in arm surgeries

Protocol summary

Study aim

By determining and comparing the combined interscalene and supraclavicular block of the brachial plexus with the interscalene and supraclavicular method alone in arm surgeries, positive steps can be taken in this regard.

Design

Clinical trial with one intervention group and two control groups, double-blind, randomized, phase 3 on 150 patients. Random block allocation with 4 blocks is used for randomization.

Settings and conduct

The study site at Shahid Beheshti Hospital in Ghoum will be a random selection between patients in need of arm surgery, to be placed in the intervention group (the group to which both nerve blocks are applied) or the control group (which is only one of the Two types of neural blocks are applied to them (random block method of 4 blocks will be used, double-blindness will include the patient himself, the data recorder and the data analyzer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient is over 18 years old, has a broken arm and needs surgery, and has American Stroke Association (ASA) 1, 2; Exclusion criteria: The patient is addicted to drugs, is pregnant, has a history of allergy to local anesthetics, and is not satisfied with the inclusion in this study.

Intervention groups

Intervention group 1: For these patients, both interscalene and supraclavicular block methods are used.
Intervention group 2: For these patients, only interscalene method is used for arm reticular block.
Intervention group 3: For these patients, only the supraclavicular method is used for blocking the neural network.

Main outcome variables

Reducing the need for painkillers to control postoperative

pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211017052786N3**

Registration date: **2022-07-06, 1401/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-06, 1401/04/15**

Update count: **0**

Registration date

2022-07-06, 1401/04/15

Registrant information

Name

Amir Hossein Moradi Rafigh

Name of organization / entity

Qom university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 25 3885 6440

Email address

amirmmr287@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the success rate of intracranial and supraclavicular combined block of the brachial plexus under ultrasound guide compared to single intracclanic and supraclavicular block in arm surgeries

Public title
Comparison of the success rate of combined block in arm surgeries

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with American Stroke Association (ASA) 1, 2
 Patients with arm fractures require surgery Patients over 18 years of age
Exclusion criteria:
 Drug addiction Patient dissatisfaction Being pregnant has a history of allergy to local anesthetics

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization using 4 blocks, randomization criterion is done using random block allocation with 4 blocks, which have all four modes (a a b b), (a b a b), (b b a a) and (b a b a) are written on four cards and the four patients are randomly grouped, respectively. The head of the ward takes the patient card out of the bag and the patients are divided into groups by lot. For example, if the lottery is (a a b b), the first and second patients are in the first group, and the third and fourth patients are in the second group, and also for the next four patients, a card is issued again.

Blinding (investigator's opinion)
Double blinded

Blinding description
The person filling out the questionnaire and the patient will not know the type and method of local anesthetic of the patient. The anesthesiologist will not interfere in the data recording or analysis process.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Ghoum University of Medical Sciences
Street address
 No.10, 13th Ave., Emam Street.
City
 Ghoum
Province
 Ghoum
Postal code
 3718913997

Approval date
2022-06-13, 1401/03/23

Ethics committee reference number
IR.MUQ.REC.1401.059

Health conditions studied

1

Description of health condition studied
Local anesthesia to the arm, forearm and hand

ICD-10 code
T81.8

ICD-10 code description
Other complications of procedures, not elsewhere classified

Primary outcomes

1

Description
Pain medication required

Timepoint
6 and 12 hours after surgery

Method of measurement
Visual analog scale

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: Interscalene block combined with superclavicular block; 100 mg of lidocaine 1% with 40

mg of marcaine 0.25. Epinephrine will be injected in half volume in the SUPRACLAVICULAR section and the other half in the INTERSCALANE section.

Category

Treatment - Other

2

Description

Control group 1: Only the superclavicular block; 100 mg of lidocaine 1% with 40 mg of marcaine 0.25% Epinephrine.

Category

Treatment - Other

3

Description

Control group 2: Interscalene block only; 100 mg of lidocaine 1% with 40 mg of marcaine 0.25 % Epinephrine.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Abbas Ahmadi

Street address

Shahid Beheshti Blvd

City

Ghoom

Province

Ghoom

Postal code

3719964797

Phone

+98 25 3612 2000

Email

Bmc@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoom University of Medical Sciences

Full name of responsible person

Mostafa vahedian

Street address

No. 83, Forth Ave., Safa Shahr Street

City

Ghoom

Province

Ghoom

Postal code

3716987366

Phone

+98 25 3285 2720

Email

vahedian58@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghoom 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

Ghoom University of Medical Sciences

Full name of responsible person

Amir Hossein Moradi Rafigh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data are specific to the present study. There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available