Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

The comparative efficacy of bupivacaine 0.5% and combination of bupivacaine 0.5% and lidocaine 2% in ultrasound guided infraclavicular block in patients with upper limb fractures: A randomized clinical trial

Protocol summary

Study aim

Comparing the efficacy of bupivacaine 0.5% and combination of bupivacaine 0.5% and lidocaine 2% in brachial plexus infraclavicular block

Design

A double-blind, randomized phase 2 clinical trial with parallel groups involving 80 patients. We utilized www.Randomization.com for the randomization process.

Settings and conduct

This study will take place in the pain operating room at Shariati Hospital in Tehran, involving 80 patients undergoing upper limb surgery. It is a double-blind, randomized clinical trial. An anesthesia technician, not involved in the study, will prepare the medications outside the operating room. Prefilled syringes will be provided to the anesthesiologist, with all drugs being indistinguishable in color and volume. The surgeon, anesthesiologist, and patients will remain unaware of the administered drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-65; body mass index (BMI) ranging from 20 to 35 kg/m² Exclusion criteria: Requiring more than one fixation in the affected limb; Allergy to opiods, acetaminophen, local anesthetics, NSAIDs; Chronic pain syndrome; Neuromascular disease; Psychological disease; drug abusers (Opiods, alcohol, other illegal drugs);chronic renal and liver disease; Loss of consciousness; pregnancy; infection at the site of procedure; Coagulation disorders or taking anticoagulant agents (except Aspirin)

Intervention groups

Control group: Infraclavicular block under ultrasonophy guide with 30ml bupivacaine 0.5%. Intervention group: Infraclavicular block under ultrasonophy guide with 20ml bupivacaine 0.5% and 10ml lidocaine 2%

Main outcome variables

Onset of complete motor and sensory block; duration of complete motor and sensory block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250422065437N1**
Registration date: **2025-09-16, 1404/06/25**
Registration timing: **prospective**

Last update: **2025-09-16, 1404/06/25**
Update count: **0**

Registration date

2025-09-16, 1404/06/25

Registrant information

Name

Pouya Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 905 458 2517

Email address

pouyasrf94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparative efficacy of bupivacaine 0.5% and combination of bupivacaine 0.5% and lidocaine 2% in ultrasound guided infraclavicular block in patients with upper limb fractures: A randomized clinical trial

Public title
The comparative efficacy of bupivacaine 0.5% and combination of bupivacaine 0.5% and lidocaine 2% in infraclavicular block

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18-65 Body mass index (BMI) ranging from 20 to 35 kg/m² Upper limb fracture

Exclusion criteria:
Requiring more than one fixation in the affected limb Allergy to opioids, acetaminophen, local anesthetics and nsaids Patients with chronic pain syndromes Patients abusing alcohol, opioids ant other anti legal drugs Renal dysfunction (edema, shortness of breath, malaise, hematuria, insomnia) Hepatic dysfunction (jaundice, ascitis, loss of consciousness, malaise, nausa, vomiting) Patients with neuromuscular disease Patients with psychological disease Loss of consciousness Pregnancy Infection at the site of procedure Patients with coagulation disease or taking anti-coagulant agents except Aspirin Reluctance to participation in this study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to either Group A (bupivacaine 0.5%) or Group B (a combination of bupivacaine 0.5% and lidocaine 2%) through the website www.randomization.com. Simple randomization will be conducted at an individualized level. After randomization, the results will be placed in concealed, opaque envelopes. An anesthesiology technician who is not involved in this study and is responsible for drug preparation will open these envelopes. The technician will prepare the drug outside of the operation room and prefilled syringes will be given to anesthesiologist. The prepared drugs are similar in term of the color and volume. The surgeon, patients, and anesthesiologist will remain blinded to the drugs used in the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
After randomization, the results will be placed in concealed, opaque envelopes. An anesthesiology technician who is not involved in this study and is responsible for drug preparation will open these envelopes. The technician will prepare the drug outside of the operation room and prefilled syringes will be given to anesthesiologist. The prepared drugs are similar in term of the color and volume. The surgeon, patients, and anesthesiologist will remain blinded to the drugs used in the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Shariati hospital, the intersection of South Kargar street and Jalal-e-Aal-e- Ahmad boulevard

City
Tehran

Province
Tehran

Postal code
1411713135

Approval date
2024-02-13, 1402/11/24

Ethics committee reference number
IR.TUMS.SHARIATI.REC.1403.117

Health conditions studied

1

Description of health condition studied
Upper limb fractures

ICD-10 code
T10

ICD-10 code description
Fracture of upper limb, level unspecified

Primary outcomes

1

Description

Onset of complete sensory block

Timepoint

Every 1 minute up to 10 minutes, every 2 minutes up to 10 minutes and then every 5 minutes up to 10 minutes or complete anethesia

Method of measurement

Hollman scale with pinprick test

2

Description

Onset of complete motor block

Timepoint

Every 5 minutes up to 30 minutes

Method of measurement

Physical examination of thumb abduction (radial nerve), third finger flexion (median nerve), fifth finger flexion (ulnar nerve) and elbow flexion (musculocutaneous)

Secondary outcomes

1

Description

Duration of sensory block

Timepoint

Every 5 minutes after the onset of complete sensory block

Method of measurement

Time between the onset of complete sensory block to first sensation of pain or patient request for painkillers.

2

Description

Duration of motor block

Timepoint

Every 5 minutes after the onset of complete motor block

Method of measurement

Time between the onset of complete motor block to return of finger functions (Grade 2 in Hollmen Scale)

Intervention groups

1

Description

Control group: Ultrasonography probe wil be placed medial to coracoid and in a sagittal plane. After visualizing the medial, lateral and posterior cord around the axillary artery, a 18 G, 10Cm needle will be inserted 1 cm medial to coracoid and 10 cm below the clavicle. After infiltration of 1ml Lidocaine 2%, 30 ml of bupivacaine 0.5% will be injected around the medial, lateral and posterior cords.

Category

Treatment - Other

2

Description

Intervention group: Ultrasonography probe wil be placed medial to coracoid and in a sagittal plane. After visualizing the medial, lateral and posterior cord around the axillary artery, a 18 G, 10Cm needle will be inserted 1 cm medial to coracoid and 10 cm below the clavicle. After infiltration of 1ml Lidocaine 2%, 30 ml of bupivacaine 0.5% in combination with 10 ml of Lidocaine 2% will be injected around the medial, lateral and posterior cords.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Pouya Sharifi

Street address

Shariati hospital, the intersection of South Kargar street and Jalal-e-Aal-e- Ahmad boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ahmadreza Jamshidi

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

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Pouya Sharifi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All collected deidentified IPD

When the data will become available and for how long
6 months after publication of the paper

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

Under which criteria data/document could be used

The analized data can only be used in purpose of designing similar studies or review articles.

From where data/document is obtainable

Dr Pouya Sharifi; 00989114582017
pouya.srf94@gmail.com

What processes are involved for a request to access data/document

Please send your request via SMS or Email to Dr Sharifi. The information will be available in 1 or 2 weeks.

Comments