

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of ultrasound guided intercostobrachial nerve block on tourniquet pain in patients undergoing axillary block in soft arm and forearm surgery

Protocol summary

Study aim

Determining the effect of ultrasound guided intercostobrachial nerve block on onset and severity of tourniquet pain in axillary block

Design

Randomized clinical trial with control group on three parallel groups, using random number table, simple sampling, sample size of 60 patients.

Settings and conduct

After monitoring and sedation, the ultrasound guided axillary block is performed with an injection of 30 ml of 1.5% lidocaine. Group1: The ultrasound guided intercostobrachial nerve block using a 2 cc of 1.5% lidocaine. Group2: intercostobrachial nerve block using conventional method without ultrasound by injecting 2 cc of 1.5% lidocaine. Group3: without intercostobrachial nerve block For all three groups, the tourniquet is closed at the arm before surgery and the tourniquet pressure is set at 100 mmHg above the systolic pressure. The patient's first reaction to the onset of tourniquet pain and its severity is recorded based on the patient's expression and VAS scoring. Pain assessment is performed on the subjects by an individual other than the block performer. Tourniquet pain assessment intervals are every 15 minutes after filling the tourniquet.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20-50, PS 1& 2, Soft tissue hand and forearm surgery, Appropriate cooperation, BMI 23-28
Exclusion criteria: Addiction, History of seizures, Coagulation problem, Neuropathy, Vasculitis, Allergy to local anesthetics, Unstable hemodynamic

Intervention groups

In all three groups, the brachial plexus axillary block is performed using ultrasound and nerve stimulator. Group 1: The intercostobrachial nerve is also blocked with ultrasound guide. Group 2: The intercostobrachial nerve is blocked in conventional way without ultrasound. Group

3: The brachial plexus block is performed without the intercostobrachial nerve block.

Main outcome variables

Onset and severity of tourniquet pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170301032837N3**

Registration date: **2020-05-11, 1399/02/22**

Registration timing: **retrospective**

Last update: **2020-05-11, 1399/02/22**

Update count: **0**

Registration date

2020-05-11, 1399/02/22

Registrant information

Name

Behrooz Zaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 7272

Email address

zaman.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

2018-06-22, 1397/04/01
Actual recruitment end date
 2019-06-21, 1398/03/31
Trial completion date
 2019-06-21, 1398/03/31

Scientific title
 The effect of ultrasound guided intercostobrachial nerve block on tourniquet pain in patients undergoing axillary block in soft arm and forearm surgery

Public title
 The effect of ultrasound guided intercostobrachial nerve block on tourniquet pain in axillary block

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 20 - 50 Hand and forearm soft tissue surgery with a minimum operation time of 90 minutes ASA 1-2 Patients BMI between 23-28 Having the right cooperation and ability to communicate with the research team
Exclusion criteria:
 Drug Addiction History of seizures Coagulation problem Upper limb neuropathy Vasculitis Unstable hemodynamic Allergy to local anesthetics

Age
 From **20 years** old to **50 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
 Target sample size: **60**
 Actual sample size reached: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple, individual randomization using random number table, so that the first patient was drawn by drawing lots in one of the three groups and the next patient was placed in one of the other two groups by using the table of random numbers based on even and odd numbers. And this sequence continued. Only the blocking researcher knew the random sequence.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 The participants in this study have no knowledge of the nerve block method and in which research group they belonged. The block was performed by the researcher and the evaluating researcher was not present in the room at the time of the block and another evaluates the outcomes without knowing which group the participant belongs to. Due to the fact that the intercostobrachial nerve block is performed during the axillary block, there is no apparent difference between patients after it is

performed.
Placebo
 Not used
Assignment
 Parallel
Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2019-04-23, 1398/02/03

Ethics committee reference number

IR.IUMS.FMD.REC.1398.046

Health conditions studied

1

Description of health condition studied

Tourniquet pain in axillary block

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

onset of pain of tourniquet

Timepoint

every 15 minutes

Method of measurement

Patient expression and Analogue Scale

2

Description

severity of tourniquet pain

Timepoint

every 15 minutes

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: ultrasound guided intercostobrachial nerve block group. In this group, after IV access and monitoring of vital signs, patients undergoing sedation with Midazolam 0.15 mg/kg and fentanyl 1.5 micrograms/kg and then is placed in a supine position with his upper extremity 90 degree angle with the body. The axillary area and the medial part of the arm are then prepared with betadine solution and draped. Using sonography (S- Nerve Ultrasound, Sonosite, Inc. WA, USA) and nerve stimulator (Plexygon, VYGON, Inc. Italy) and needle number 21 (Locoplex, VYGON, France), at first four nerves of the median, ulna, radial, and musculoskeletal nerves are blocked, each with 7 cc of lidocaine 1.5 percent, and then the intercostobrachial nerve above the deep fascia are blocked with ultrasound and 2 cc of 1.5% lidocaine.

Category

Prevention

2

Description

Intervention group 2: intercostobrachial nerve block without ultrasound group. In this group, after IV access and monitoring of vital signs, patients undergoing sedation with Midazolam 0.15 mg/kg and fentanyl 1.5 micrograms/kg and then is placed in a supine position with his upper extremity 90 degree angle with the body. The axillary area and the medial part of the arm are then prepared with betadine solution and draped. Using sonography (S- Nerve Ultrasound, Sonosite, Inc. WA, USA) and nerve stimulator (Plexygon, VYGON, Inc. Italy) and needle number 21 (Locoplex, VYGON, France), first four nerves of the median, ulna, radial, and musculoskeletal nerves were blocked, each with 7 cc of 1.5% lidocaine, and then the intracostobrachial nerve was blocked without ultrasound and by the conventional method, by touching the pulse of the axillary artery and injection of 2 cc of 1.5% lidocaine, on the pulse of the artery and under the skin.

Category

Prevention

3

Description

Control group: without intercostobrachial nerve block. In this group, after IV access and monitoring of vital signs, patients undergoing sedation with Midazolam 0.15 mg/kg and fentanyl 1.5 micrograms/kg and then is placed in a supine position with his upper extremity 90 degree angle with the body. The axillary area and the medial part of the arm are then prepared with betadine solution and draped. Using sonography (S- Nerve Ultrasound,

Sonosite, Inc. WA, USA) and nerve stimulator (Plexygon, VYGON, Inc. Italy) and needle number 21 (Locoplex, VYGON, France), four nerves of the median, ulna, radial, and musculoskeletal nerves are blocked, each with 7 cc of 1.5% lidocaine. The intercostobrachial nerve block is not performed in this group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-e Fatemeh Hospital

Full name of responsible person

Dr. Noor ahmad Latifi

Street address

21st. street. Assadabadi Ave.

City

Tehran

Province

Tehran

Postal code

1433933118

Phone

+98 21 8871 7272

Fax

+98 21 8810 7658

Email

crtfatima@iums.ac.ir

Web page address

<https://crtfatima.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. seyed abbas motevalian

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2030

Fax

+98 21 8862 2692

Email

ivco@iums.ac.ir

Web page address

<https://iums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Behrooz Zaman

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hazrat-e fatemeh hospital, 21st street, Asadabadi Ave

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8810 7658

Email

zaman.b@iums.ac.ir

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8810 7658

Email

zaman.b@iums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Behrooz Zaman

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hazrat-e Fatemeh Hospital, 21st Street, Asadabadi Ave.

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8810 7658

Email

zaman.b@iums.ac.ir

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after people have not been identified.

When the data will become available and for how**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Behrooz Zaman

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hazrat-e Fatemeh Hospital, 21st Street, Asadabadi Ave.

long

Start of access period from 1399

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Academic and scientific researchers can use it for future researches.

From where data/document is obtainable

zaman.b@iums.ac.ir

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

Applicants should send the required request and explanation via e-mail to the registrant, which will be sent within a maximum of one month, if they meet the above requirements.

Comments

For academic and scientific researchers, we will provide any assistance we can.