Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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)

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+98 21 8871 7272

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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

۱۴۴۹۶۱۴۵۳۵

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 extrimity 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 extrimity 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 extrimity 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
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Sponsors / Funding sources

1

Sponsor

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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
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
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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
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

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.