Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of the effect of axillary block alone versus axillary block + subcutaneous injection of local anesthetic on tourniquet pain relief in upper limb orthopedic surgeries

Protocol summary

Study aim

Determining the effect of axillary block + subcutaneous lidocaine infiltration on reducing tourniquet pain in orthopedic surgeries of the forearm, wrist or hand with using tourniquet

Design

A randomized, double-blinded, controlled clinical trial with a parallel group enrolled 78 patients. Random number table is used for randomization.

Settings and conduct

This study is performed in Akhtar Hospital . The severity of the tourniquet pain is measured immediately after inflating the tourniquet and then every 15 minutes with the Verbal Rating Scale. The first complaint of tourniquet pain is recorded during surgery. If the patient complains of tourniquet pain or VRS>1, intravenous fentanyl and, if necessary, ketamine is injected. If the pain persists, propofol is infused and if there is no response, general anesthesia is performed. Doses of fentanyl, ketamine, and propofol are also recorded.Participants, researchers and outcome assessors are unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

78 patients aged 15 years and older ASA class I- Ⅲ scheduled for orthopedic surgery of the forearm, wrist or hand under the sono-guided axillary block with the use of tourniquets are included. Cases of rejection, lidocaine hypersensitivity, coagulation disorders, opium addiction, non-cooperation, block site infection, BMI≥30, DVT, sickle cell anemia, tourniquet inflation time of less than 30 minutes are excluded.

Intervention groups

Patients are randomly divided into two equal groups of axillary block alone and axillary block + subcutaneous infiltration of lidocaine. In the axillary block alone group, 5 ml of normal saline and in the Intervention group, 5 ml of 1.5% lidocaine are injected subcutaneously in the upper inner part of the upper arm.

Main outcome variables

The severity of tourniquet pain and the total amount of administered fentanyl, ketamine and propofol.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131108015322N6**
Registration date: **2022-02-06, 1400/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-06, 1400/11/17**
Update count: **0**

Registration date

2022-02-06, 1400/11/17

Registrant information

Name

Shideh Dabir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2595

Email address

sdabir@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of axillary block alone versus axillary block + subcutaneous injection of local anesthetic on tourniquet pain relief in upper limb orthopedic surgeries

Public title

The effect of axillary block with subcutaneous injection of local anesthetic on tourniquet pain relief

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA class I- III Patient acceptance Unilateral orthopedic surgery of forearm or wrist or hand Tourniquet inflation time more than 30 minutes Patients 15 years and older

Exclusion criteria:

ASA class more than III Patient refusal Allergy to lidocaine Age less than 15 years Coagulopathy Opium addiction Lack of patient cooperation Infection at block site BMI≥30 Patients with DVT Patients with sickle cell anemia Tourniquet inflation time less than 30 minutes

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly assigned to 1 of 2 groups following simple randomization by using a random numbers table. The allocation sequence is concealed in sealed envelopes. In the operating room, the envelope is opened by an investigator with no clinical involvement in the trial.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and assignment of patients in each group is done by a person not involved in the study. The investigators and persons who measures the outcome in two groups are also kept blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Building No. 2, 5th floor, Office in Research Affairs, shahid Beheshti University of Medical sciences, Shahid Chamran Highway, Yemen St., Arabi St., next to Taleghani Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.SBMU.MSP.REC.1400.476

Health conditions studied

1

Description of health condition studied

Prevention of upper arm tourniquet pain during orthopedic surgery performed under axillary brachial plexus block.

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Intraoperative severity of tourniquet pain

Timepoint

Immediately after inflating the tourniquet and then every 15 minutes during operation

Method of measurement

Verbal Rating Scale 0-4

Secondary outcomes

1

Description

Total intraoperative dose of fentanyl and ketamine and propofol

Timepoint

From the time of inflating the tourniquet to the end of

the operation

Method of measurement

Calculating the sum of injected doses

2

Description

Duration of tourniquet inflation

Timepoint

From inflating the tourniquet to deflating it during surgery

Method of measurement

The time interval between inflation and deflation of tourniquet is measured in minutes.

Intervention groups

1

Description

Control group: axillary block + subcutaneous infiltration of 5 ml of normal saline in the upper inner part of the upper arm

Category

Treatment - Other

2

Description

Intervention group: axillary block + subcutaneous infiltration of 5 ml of lidocaine 1.5 % in the upper inner part of the upper arm

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Faramarz Mosaffa

Street address

Akhtar Hospital, Shariati Ave., Pole- Rumi St., Sharifimanesh St., Azar dead end

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2664 0307

Email

faramarzmosaff@yahoo.com

Web page address

http://amc.sbmu.ac.ir/#

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Dabbagh

Street address

Fourth floor, Anesthesiology Research Center, Taleghani Hospital, Arabi St., Yemen St., Velenjak

City

Tehran

Province

Tehran

Postal code

1985717413

Phone

+98 21 2303 1550

Email

alidabbagh@sbmu.ac.ir

Web page address

https://arc.sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shideh Dabir

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

2nd floor, Department of Anesthesiology, Taleghani Hospital, Arabi St., Yaman St. Velenjak

City

Tehran

Province

Tehran

Postal code
1985717413

Phone
+98 21 2303 1550

Email
shdabir@yahoo.com

Web page address
http://taleghani.sbmu.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shideh Dabir

Position
Professor

Latest degree
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Other areas of specialty/work
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Tehran

Postal code
1985717413

Phone
+98 21 2243 2595

Email
shdabir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shideh Dabir

Position
Professor

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+98 21 2243 2595

Email
shdabir@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan
No - There is not 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
Undecided - It is not yet known if there will be 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