

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of neostigmine and placebo in combination with ropivacaine on the onset and severity of axillary block in patients undergoing hand and forearm surgery.

Protocol summary

Study aim

Comparison of the effect of neostigmine and placebo in combination with ropivacaine on the onset and severity of axillary block in patients undergoing hand and forearm surgery.

Design

This study is a clinical trial with a control group, with parallel groups, double-blind, randomized on 40 patients. We use the block randomization method for randomization.

Settings and conduct

After obtaining informed consent, patients are divided into two groups. After standard monitoring is connected, 200cc of Ringer's serum is injected, patients are sedated by injecting 0.15mg/kg midazolam and 1.5µg/kg fentanyl. Then, with the simultaneous use of ultrasound and neurostimulator, the brachial plexus nerves were identified in the axillary region, and in the first group, 30 cc of 0.5% ropivacaine and 500 µg of neostigmine (31 cc in total) were injected for axillary block. In the second group, 30 cc of ropivacaine 0.5% and 1 cc of distilled water are injected as a placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for hand and forearm surgery; patients with ASA I, II anesthesia level. Exclusion criteria: Allergy to local anesthetics congenital and acquired neuromuscular diseases.

Intervention groups

Intervention group: patients undergoing hand and forearm surgery in which ropivacaine and neostigmine are used for axillary block. Control group: patients undergoing hand and forearm surgery in which ropivacaine and placebo are used for axillary block.

Main outcome variables

Regional anesthesia onset time; regional anesthesia effect intensity; pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221017056211N1**

Registration date: **2022-10-24, 1401/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-24, 1401/08/02**

Update count: **0**

Registration date

2022-10-24, 1401/08/02

Registrant information

Name

Elham Shasti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

shastielham@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of neostigmine and placebo in combination with ropivacaine on the onset and severity of axillary block in patients undergoing hand and forearm surgery.

Public title

The effect of neostigmine drug on the onset and intensity of regional anesthesia in upper limb surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate patients for hand and forearm surgery
Patients with ASA I, II anesthesia level

Exclusion criteria:

Allergy to local anesthetics
Congenital and acquired neuromuscular diseases

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block 4, we divide patients into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B

Placebo

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

Hemat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

8874113911

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.IUMS.FMD.REC.1401.120

Health conditions studied

1

Description of health condition studied

Upper extremity surgery

ICD-10 code

L02.52

ICD-10 code description

Furuncle hand

Primary outcomes

1

Description

Regional anesthesia onset time

Timepoint

During of surgery

Method of measurement

Using a timer

2

Description

Regional anesthesia intensity

Timepoint

During surgery

Method of measurement

A questionnaire designed by the researcher using the patient's information and the anesthesiologist's opinion.

Secondary outcomes

1

Description

Pain from surgery

Timepoint

During surgery

Method of measurement

Using the Visual Analogue Scale pain questionnaire

Intervention groups

1

Description

Intervention group: After obtaining informed consent, patients are divided into two groups. After standard monitoring is connected, 200cc of Ringer's serum is injected, patients are sedated by injecting 0.15mg/kg midazolam and 1.5µg/kg fentanyl. Then, with the simultaneous use of ultrasound and neurostimulator, the brachial plexus nerves were identified in the axillary region, and in the first group, 30 cc of 0.5% ropivacaine (Made by Jalinous Pharmaceutical Company) and 500 µg of neostigmine (Made by Jalinous Pharmaceutical Company) (31 cc in total) were injected for axillary block. Then, the onset time and intensity of regional anesthesia are recorded using a suitable questionnaire.

Category

Treatment - Drugs

2

Description

Control group: After obtaining informed consent, patients are divided into two groups. After standard monitoring is connected, 200cc of Ringer's serum is injected, patients are sedated by injecting 0.15mg/kg midazolam and 1.5µg/kg fentanyl. Then, with the simultaneous use of ultrasound and neurostimulator, the brachial plexus nerves were identified in the axillary region, and in the first group, 30 cc of 0.5% ropivacaine (Made by Jalinous Pharmaceutical Company) and One cc of distilled water (Made by Jalinous Pharmaceutical Company) (31 cc in total) were injected for axillary block. Then, the onset time and intensity of regional anesthesia are recorded using a suitable questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Elham Shasti

Street address

Anesthesia Department, Firouzgar Hospital ,Beh-afarin street

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Phone

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Email

Shastielham@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hosein Keyvani

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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

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elham Shasti

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Elham Shasti

Position

Consultant

Latest degree

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Other areas of specialty/work

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

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Full name of responsible person

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Position

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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

Undecided - It is not yet known if there will be 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

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