Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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 anestheticsl 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
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8894 6762
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
Street address
Hemat Highway next to Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8670 5503
Email
keyvani.h@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
Elham Shasti
Position
Consultant
Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology
Street address
Anesthesia Department, Firouzgar Hospital ,Behafarin street
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8894 6762
Email
Shastielham@yahoo.com

Person responsible for scientific 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
Street address
Anesthesia Department, Firouzgar Hospital ,Behafarin street
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8894 6762
Email
Shastielham@yahoo.com

Person responsible for updating data

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
Street address
Anesthesia Department, Firouzgar Hospital ,Behafarin street
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8894 6762
Email
Shastielham@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
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