

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of two very low doses of naloxone in combination with ropivacaine on the onset ,severity and duration of axillary block in patients with hand and forearm surgery

Protocol summary

Study aim

Comparison of two very low doses of naloxone in combination with ropivacaine on the onset ,severity and duration of axillary block in patients with hand and forearm surgery

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 75 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

In this research, all patients requiring hand and forearm surgery, referred to Rasoul Akram Hospital in Tehran, will be included in the study. Patients will be randomly divided into 3 groups based on blocks of 6. The sample size for each study group is 20 people. A total of 60 patients will be examined. Patients, surgeon and data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for hand and forearm surgery, Age between 18-70 years. Exclusion criteria: Anemia, sensitivity to local anesthetic drugs, congenital and acquired neuromuscular diseases, history of seizures, drug addiction, heart diseases and any digestive system disorders.

Intervention groups

Patients are divided into three groups of 20 and undergo axillary block guided by ultrasound and neurostimulator. In the first intervention group, axillary block is performed using ropivacaine in combination with naloxone 4 micrograms. In the second intervention group, axillary block is performed using ropivacaine combined with naloxone 0.4 micrograms. In the control group, axillary block is performed using ropivacaine combined with normal saline (placebo).

Main outcome variables

Pain score; The amount of drug use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170105031787N6**

Registration date: **2023-05-03, 1402/02/13**

Registration timing: **prospective**

Last update: **2023-05-03, 1402/02/13**

Update count: **0**

Registration date

2023-05-03, 1402/02/13

Registrant information

Name

Mohammad-Reza Yasinzadeh

Name of organization / entity

Iran university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		the letter envelopes are glued and placed in a box, respectively. the door At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.	
Scientific title	Comparison of two very low doses of naloxone in combination with ropivacaine on the onset ,severity and duration of axillary block in patients with hand and forearm surgery	Blinding (investigator's opinion)	Double blinded
Public title	Two very low doses of naloxone in combination with ropivacaine on the onset ,severity and duration of axillary block	Blinding description	The surgeon and the patients will be unaware and blind of the type of drug used in the axillary block. To hide similar and identical sera, it was used without drug name label and only with code. Patients will be aware that they will be randomly assigned to one of three treatment groups, but will not know which treatment will be provided in that group. Patients will be assigned to one of three groups using a random number table. The surgeon also knows that axillary block will be performed by three different methods for the patients, but he will not know which method will be performed for each patient. The person in charge of data collection, the analyst, and the outcome evaluator will collect and analyze the information based on groups 1, 2, and 3, and will not know the type of treatment provided in the groups and will be kept blind.
Purpose	Treatment	Placebo	Used
Inclusion/Exclusion criteria		Assignment	Parallel
Inclusion criteria:	Candidate patients for hand and forearm surgery Age between 18-70 years	Other design features	
Exclusion criteria:	Anemia Sensitivity to local anesthetic drugs Congenital and acquired neuromuscular diseases History of seizures Drug addiction Heart diseases Any digestive system disorders.	Secondary Ids	empty
Age	From 18 years old to 70 years old	Ethics committees	
Gender	Both	1	
Phase	3	Ethics committee	
Groups that have been masked	• Participant • Investigator • Outcome assessor • Data analyser	Name of ethics committee	Ethics committee of Iran University of Medical Sciences
Sample size	Target sample size: 60	Street address	Iran University of Medical Sciences, Hemmat Highway
Randomization (investigator's opinion)	Randomized	City	Tehran
Randomization description	Patients will be randomly divided into 3 groups. The randomization tool will be a random sequence generation software called SIS. In addition to simple randomization, these random sequence generation softwares are capable of generating random sequences using the block method. Block randomization method will be used for randomization. Block randomization is for the purpose of making sure that exactly equal number of participants enter the study groups. The advantages of block randomization are that the balance of the number of participants in each group is guaranteed. For this purpose, 6 blocks will be formed and in each block 2 people from intervention group 1, 2 people from intervention group 2 and 2 people will be placed in the control group. A total of 10 blocks will be considered to reach the sample size. Random allocation concealment will be done using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally,	Province	Tehran
		Postal code	1449614535
		Approval date	2023-01-04, 1401/10/14
		Ethics committee reference number	IR.IUMS.FMD.REC.1401.498
		Health conditions studied	
		1	
		Description of health condition studied	hand and forearm surgery

ICD-10 code

S50-S59

ICD-10 code description

Injuries to the elbow and forearm

Primary outcomes

1

Description

Pain score

Timepoint

Upon entering recovery

Method of measurement

Based on NRS scale

2

Description

The amount of drug use

Timepoint

In the first 24 hours after the surgery

Method of measurement

Based on the information in the patient's file

Secondary outcomes

1

Description

Duration of numbness

Timepoint

During surgery

Method of measurement

Based on the information in the patient's file

2

Description

The first time to ask for drugs

Timepoint

During surgery

Method of measurement

Based on the information in the patient's file

3

Description

Ramsy sedation scale

Timepoint

During surgery and upon entering recovery

Method of measurement

Based on the information in the patient's file

4

Description

Patient's satisfaction

Timepoint

After surgery

Method of measurement

Based on the Likert scale

Intervention groups

1

Description

Intervention group 1: The axillary block will be performed using 29 cc of ropivacaine 0.5% (manufacturer: Varian Pharmamed) plus 1 cc of naloxone 4 micrograms (manufacturer: Tolid Daroo).

Category

Treatment - Drugs

2

Description

Intervention group 2: The axillary block will be performed using 29 cc of ropivacaine 0.5% (manufacturer: Varian Pharmamed) plus 1 cc of naloxone 0.4 micrograms (manufacturer: Tolid Daroo).

Category

Treatment - Drugs

3

Description

Control group: The axillary block will be performed using 29 cc of ropivacaine 0.5% (manufacturer: Varian Pharmamed) plus 1 cc of normal saline (30 cc in total).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-Akram Hospital

Full name of responsible person

Mahshad Ghezel Bash

Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

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Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein 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

Mahshad Ghezel Bash

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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