Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of duration of analgesia in Axillary block with Lidocaine and a mixture of Lidocaine and Granistron in patients requiring lower elbow surgery

Protocol summary

Study aim
Determining the duration of analgesia in axillary block with Lidocaine in comparison with the combination of Lidocaine and Granistron in patients requiring lower elbow surgery

Design
This Clinical trial has control and intervention groups. The intervention group will receive a combination of Lidocaine and Granisetron and the control group will receive Lidocaine only. The trial will be done in the form of a double-blind and randomized study, on 90 patients. Block randomization with block size 4 (With random sequence in the block) and allocation ratio 1:1, will be done. Allocation of patients to intervention and control groups will be parallel.

Settings and conduct
The study was performed in the Orthopedic ward of Razi, Golestan and Imam Khomeini hospitals in Ahvaz for one year (from March 2018 to March 2019). This Clinical trial has control and intervention groups. The intervention group will receive a combination of Lidocaine and Granisetron and the control group will receive Lidocaine only. The study was performed in a double blinded form. Participants and health care personnel in the study were blind to the injected drugs.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18-58 years; Being candidate for elbow and under elbow surgery; Level of consciousness above 14 according to Glasgow criteria Exclusion criteria: Allergy to Lidocaine and Granistron; Taking drugs that interact with Lidocaine and Granistron; Injury or infection at the injection site; History of coagulation diseases

Intervention groups
In the control group, 40 cc of Lidocaine solution was injected after applying the syringe with Epinephrine. In the intervention group, in addition to Lidocaine solution, 2 mg of Granistron was injected into patients simultaneously.

Main outcome variables
Pain score; Sensory block onset; Motor block onset; Duration of sensory block; Duration of movement block

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200402046916N1**
Registration date: **2020-11-06, 1399/08/16**
Registration timing: **retrospective**

Last update: **2020-11-06, 1399/08/16**
Update count: **0**

Registration date
2020-11-06, 1399/08/16

Registrant information

Name
majid bozar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8770 5402

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-24, 1397/10/03

Expected recruitment end date
2019-12-24, 1398/10/03

Actual recruitment start date

2018-12-31, 1397/10/10

Actual recruitment end date

2020-01-05, 1398/10/15

Trial completion date

2020-03-15, 1398/12/25

Scientific title

Comparison of duration of analgesia in Axillary block with Lidocaine and a mixture of Lidocaine and Granistron in patients requiring lower elbow surgery

Public title

Comparison of the effect of Lidocaine and a mixture of Lidocaine and Granisetron on axillary block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for elbow and below elbow surgery Patients between the ages of 18-58 years Patients whose level of consciousness is above 14 according to the Glasgow standard

Exclusion criteria:

Patients who are allergic to Lidocaine and granisterone Patients who take drugs that interact with Lidocaine and Granistron Patients who have a lesion or infection at the injection site Patients with a history of coagulopathy

Age

From **18 years** old to **58 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Method: Simple block randomization with block size 4 and allocation ratio 1:1 (One sample was placed in the intervention group and one sample in the control group until sampling was completed) . Balanced Block Randomization method with block size 4 (With random sequence in the block) and one-to-one allocation was used to place patients in the two groups. The randomization unit was individual. Codes assigned to patients in both groups were kept in sealed envelopes and provided to the ward secretary. Patients and health care providers did not know about these codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and health providers will be blinded to the intervention. Codes assigned to patients in both groups were kept in sealed envelopes and provided to the ward secretary. Patients and health care providers did not know about these codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan highway, Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

6135853415

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.AJUMS.REC.1398.462

Health conditions studied

1

Description of health condition studied

Patients require lower elbow surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The onset of sensory block

Timepoint

The onset of sensory block will be measured at 6 and 12 hours after the intervention and also at the time of the first need for analgesia.

Method of measurement

By examining and the PIN PRINK test

2

Description

The onset of motor block

Timepoint

The onset of motor block will be measured at 6 and 12 hours after the intervention and also at the time of the first need for analgesia.

Method of measurement
Examination and the patient's ability in adduction flexion and finger extension

3

Description
The duration of sensory block
Timepoint
The duration of sensory block will be measured at 6 and 12 hours after the intervention and also at the time of the first need for analgesia.
Method of measurement
By examination and PIN PRINK test

4

Description
The duration of motor block
Timepoint
The duration of motor block will be measured at 6 and 12 hours after the intervention and also at the time of the first need for analgesia.
Method of measurement
Examination and the patient's ability in adduction flexion and finger extension

5

Description
Pain score
Timepoint
The pain score will be measured at 6 and 12 hours after the intervention and also at the time of the first need for analgesia.
Method of measurement
By interviewing and the Numeric Rating Scale system

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before the intervention, every 10 minutes during the intervention and 2 and 6 hours after
Method of measurement
Measuring patient's blood pressure by monitoring and a Sphygmomanometer

2

Description
Heart rate
Timepoint
Before the intervention, every 10 minutes during the intervention and 2 and 6 hours after
Method of measurement
Measuring the patient's heart rate by monitoring and pulse counting

3

Description
Respiration
Timepoint
Before the intervention, every 10 minutes during the intervention and 2 and 6 hours after
Method of measurement
Measuring the patient's respiration by monitoring, using the number of breaths per minute

4

Description
Time for taking analgesia
Timepoint
6 and 12 hours after the intervention
Method of measurement
Based on pain scores, analgesic is injected in a pain score of 6 or more.

Intervention groups

1

Description
Intervention group: 5 mg / kg Lidocaine 0.5% is diluted with 0.9% normal saline to 40 cc. After impregnating the syringe with epinephrine, 40 cc of Lidocaine solution and 2 mg of Granistron is injected into patients simultaneously. Axillary block is performed by ultrasonography with linear transducer using short-axis view with in-plane technique. The drugs are manufactured by Caspian Company.
Category
Treatment - Surgery

2

Description
Control group: 5 mg / kg Lidocaine 0.5% is diluted with 0.9% normal saline to 40 cc. After impregnating the syringe with epinephrine, 40 cc of Lidocaine solution is injected. Axillary block is performed by ultrasonography with linear transducer using short-axis view with in-plane technique. The drugs are manufactured by Caspian Company.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Majid Bozar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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

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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