Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

A clinical trial of comparing dexamethasone plus lidocaine with lidocaine alone on the quality of Bier's Block in orthopedic patients for upper extremity surgeries

Protocol summary

Summary

Aim: Comparing the effect of adding dexamethasone to lidocaine with lidocaine alone on the quality of intravenous regional anesthesia for upper limb orthopedic surgeries. Type of study: Randomized controlled clinical trial, double blinded (patient and the resident responsible for data collection were unaware of the type of trial drugs) in two groups, 3rd stage, one centered, recruiting phase completed. Inclusion criteria: ASA class I-II, 15 to 65 years old, upper limb injuries distal to the elbow. Exclusion criteria: Muscle-nerve-skin diseases, allergic reactions, general anesthesia requirement due to inadequate regional anesthesia. Methods: A double tourniquet was fastened over the same arm of the extremity to be operated. An intravenous line on the back of the same hand was used to inject the local anesthetic solution diluted with distilled water to a volume of 40 cc; containing 3 mg/kg lidocaine in control group and 8 mg dexamethasone added to 3 mg/kg lidocaine in the study group. For sedation 2 mg midazolam is injected intravenously. The sensory block along the extension of the radial, ulnar and median nerves was documented. If needed fentanyl was administered maximally 2 times. In the case of inadequate regional block and sedation, general anesthesia was applied and the patient was excluded from the study. Main variables: Sensory block onset, sensory block recovery, time to first request of analgesia in recovery, the amount of opioid usage during operation and patient satisfaction. Outcomes: Increasing the quality of block.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052928158N1**

Registration date: **2017-05-17, 1396/02/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-17, 1396/02/27

Registrant information

Name

Bibimona Razavi

Name of organization / entity

Hormozgan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of comparing dexamethasone plus lidocaine with lidocaine alone on the quality of Bier's

Block in orthopedic patients for upper extremity surgeries

Public title
Evaluating the effect of adding dexamethasone to lidocaine in improving the quality of the upper extremity anesthesia through venous injection (Bier's Block) in orthopedic operations
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: ASA class I-II, 15 to 65 years old, upper limb injuries distal to the elbow. Exclusion criteria: Muscle-nerve-skin diseases, allergic reactions, general anesthesia requirement due to inadequate regional anesthesia.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Patients will randomly assigned into two groups using computerized randomization. Patients and outcome assessors are unaware of patients allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences
Street address
Shahid Mohammadi Hospital, Jomhoori-e Eslami Boulevard
City
Bandar Abbas
Postal code
Approval date
2015-10-23, 1394/08/01
Ethics committee reference number
HUMS .REC. 1394.95

Health conditions studied

1

Description of health condition studied
Intravenous regional anesthesia
ICD-10 code
(S60-S69)
ICD-10 code description
Injuries to the wrist and hand AND Injuries to the elbow and forearm

Primary outcomes

1

Description
Sensory block onset
Timepoint
30 seconds
Method of measurement
Pinprick test (needle 22 gauge bevel)

2

Description
sensory block recovery
Timepoint
30 seconds
Method of measurement
pinprick test (with needle 22 gauge bevel)

3

Description
Time to first request of analgesic in recovery
Timepoint
15, 30, 45, and 60 minutes after intervention
Method of measurement
minutes

4

Description
Intraoperative opium consumption
Timepoint
1 hours
Method of measurement
Total fentanyl consumption dose (micro-gram)

5

Description
Patients satisfaction
Timepoint
1 hours
Method of measurement
Excellent: if there is no complain during operation. Good: if there is mild discomfort but without the need of analgesia during operation. Moderate: if the patient has

discomfort and needs analgesia. Poor: If the patient receives 2 doses of fentanyl (1 microgram/kg) but still has discomfort, and requires sedative doses of propofol (25-75 microgram/kg/min) to tolerate the procedure.

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Baseline, 5 minutes after tourniquet inflation, 20 minutes after tourniquet inflation, immediately after tourniquet deflation, in recovery
Method of measurement
Non-invasive automatic blood pressure monitoring device

2

Description
Diastolic blood presure
Timepoint
Baseline, 5 minutes after tourniquet inflation, 20 minutes after tourniquet inflation, immediately after tourniquet deflation, in recovery
Method of measurement
Non-invasive automatic blood pressure monitoring device

3

Description
Mean arterial blood pressure
Timepoint
Baseline, 5 minutes after tourniquet inflation, 20 minutes after tourniquet inflation, immediately after tourniquet deflation, in recovery
Method of measurement
Non-invasive automatic blood pressure monitoring device

4

Description
Heart rate
Timepoint
Baseline, 5 minutes after tourniquet inflation, 20 minutes after tourniquet inflation, immediately after tourniquet deflation, in recovery
Method of measurement
Beats per minute by an electrocardiographic monitoring device

Intervention groups

1

Description
A double tourniquet was fastened over the arm of the extremity which needed surgery. In the control group local anesthetic solution, 3mg/kg lidocaine with distilled water up to a volume of 40 cc was injected from an intravenous line at the back if the same hand.
Category
Treatment - Drugs

2

Description
A double tourniquet was fastened over the arm of the extremity which needed surgery. In the study group local anesthetic solution, 3 mg/kg lidocaine and 8 mg dexamethasone with distilled water up to a volume of 40 cc was injected from an intravenous line at the back if the same hand.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Dr. Bibi Mona Razavi
Street address
Shahid Mohammadi hospital, Jomhoori-e Eslami Boulevard
City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hormozgan University of Medical Sciences
Full name of responsible person
Abdulazim Nejatizadeh
Street address
Deputy of Research, Shahid Mohammadi Hospital, Jomhoori-e Eslami Boulevard
City
Bandar Abbas
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Hormozgan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Hormozgan University of Medical Sciences
Full name of responsible person
Dr. Manuchehr Kamali
Position
Anesthesiologiy specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty