

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)

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+98 76 3223 6367

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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

HUMS .REC. 1394.95

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

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 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

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 of 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 of 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***Phone**

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Hormozgan University of Medical Sciences

Full name of responsible person

Dr. Manuchehr Kamali

Position

Anesthesiology specialist

Other areas of specialty/work**Street address**Shahid Mohammadi hospital, Jomhoori-e Eslami
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Hormozgan University of Medical Sciences

Full name of responsible person

Dr. Abbas Moallemy

Position

Associated professor, fellowship of pain medicine

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Postal code

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

Hormozgan University of Medical Sciences

Full name of responsible person

Dr. Bibi Mona Razavi

Position

Anesthesia resident

Other areas of specialty/work**Street address**Shahid Mohammadi hospital, Jomhoori-e Eslami
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Web page address**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*