Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Evaluating the Effect of adding Dexamethasone to Lidocaine 1.5% in Infraclavicular Block with Ultrasound Guide on the Onset of Effect and Duration of Block

Protocol summary

Study aim
Evaluating the Effect of adding Dexamethasone to Lidocaine 1.5% in Infraclavicular Block on the Onset of Effect and Duration of Block

Design
Clinical trial with control group, with parallel, double-blind and randomized groups

Settings and conduct
In this study, patients who have referred to Kowsar Hospital in Sanandaj for treatment of upper limb fractures (below the arm) are assessed. Therefore, dividing patients into intervention and control groups randomly, the effect of adding dexamethasone to lidocaine to perform infraclavicular block at the onset and duration of the effect is evaluated. This study was performed in a double-blind manner and patients, outcome assessors and physicians were not studied by grouping patients.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1.Age 18 to 60 years old 2. Placement in ASA classification of class 1 and 2 3. Need orthopedic surgery to repair an upper limb fracture (below the arm) Non-Inclusion Criteria: 1. Coagulation disorder based on tests (INR> 1.4) 2. History of liver, kidney, peptic ulcer disease 3. History of uncontrolled diabetes 4. Infection in the area of nerve block 5. Hypersensitivity to local anesthetics or dexamethasone 6. History of long-term use of corticosteroids 7. History of drug addiction or drug use 8. Pregnancy

Intervention groups
Intervention Group: 33 ml of 1.5% lidocaine solution (495 mg) and 2 ml of dexamethasone (Dexadic - Caspian Supply Pharmaceutical Company) (8 mg) will be used for Infraclavicular Block . Control Group: 33 ml of 1.5% lidocaine solution (495 mg) and 2 ml of normal saline (placebo) will be used for Infraclavicular Block .

Main outcome variables
1. The onset of analgesia and immobility 2. The duration of analgesia and immobility

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220120053774N1**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **prospective**

Last update: **2022-02-05, 1400/11/16**
Update count: **0**

Registration date
2022-02-05, 1400/11/16

Registrant information

Name
Aram Khaledian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3361 1232

Email address
aramkhaledian@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effect of adding Dexamethasone to Lidocaine 1.5% in Infraclavicular Block with Ultrasound Guide on the Onset of Effect and Duration of Block

Public title

The effect of adding dexamethasone to lidocaine in infraclavicular block on the onset and duration of block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years old ASA classification Status 1 and 2 Need to orthopedic surgery to repair an upper limb fracture (below the arm)

Exclusion criteria:

Coagulation disorder (INR> 1.4) History of liver, kidney, peptic ulcer disease History of uncontrolled diabetes Infection in the area of nerve block History of hypersensitivity to local anesthetics or dexamethasone History of long-term use of corticosteroids History of addiction or narcotic use Pregnancy Changing the anesthesia plan during surgery from nerve block to general anesthesia Hemodynamic instability Patient request to leave the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done randomly using computer generated random numbers. Thus, each "odd number" produced belongs to group 1 (intervention group) and each randomly generated "even number" belongs to group 2 (patient placement in the control group).

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind this study, patients do not know which study groups they are in. Also, the combination of lidocaine-dexamethasone solution or lidocaine-placebo, in the same volume of 36 ml, is prepared and coded by a nurse colleague who is not present in the study. The anesthesiologist who also performs the procedure is not aware of the prescription drug and the grouping of patients. Patients will be evaluated by an anesthesia assistant who is not in the study group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6617913446

Approval date

2021-12-21, 1400/09/30

Ethics committee reference number

IR.MUK.REC.1400.233

Health conditions studied

1

Description of health condition studied

Upper limb fractures

ICD-10 code

S.52

ICD-10 code description

Injuries to the elbow and forearm

Primary outcomes

1

Description

The onset of analgesia

Timepoint

Every 5 minutes to complete block.

Method of measurement

Using a question from the patient and using a pinprick test, using a needle with mild skin irritation (normal sense of zero score, inability to understand pinprick score 1 and lack of sense of touch score 2) will be used. To ensure analgesia, a score of 1 sensory block is acceptable. The patient's sensory block is assessed and the patient's onset of analgesia is recorded in a questionnaire. Motion block is also measured using a modified bromage scale. In this way, points are given from zero to 4 (full strength of related muscles, score 4,

decrease in muscle strength but the ability to move against resistance 3, ability to move against gravity 2, slight muscle jump 1 and inability to move zero score).

2

Description
The duration of analgesia
Timepoint
Every 5 minutes to 30 minutes after injection of block solution, during surgery and then every 30 minutes until complete removal of sensory and motor block in recovery and ward
Method of measurement
Pain in the recovery ward using the Visual Analogue Scale (VAS), which is a numerical scoring scale (zero painless to 10 highest pain).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 33 ml of 1.5% lidocaine solution (495 mg) and 2 ml of dexamethasone (Dexadic - Caspian Supply Pharmaceutical Company) (8 mg) will be used for Infraclavicular Block .
Category
Treatment - Drugs

2

Description
Control group: 33 ml of 1.5% lidocaine solution (495 mg) and 2 ml of normal saline (placebo) will be used for Infraclavicular Block .
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Farzad Sarshivi
Street address
Hamdi Blvd - Pasdaran Blvd
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Sponsors / Funding sources

1

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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
Sanandaj 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
Sanandaj University of Medical Sciences
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable