# 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**

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Iran (Islamic Republic of)

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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**

**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**
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
**Full name of responsible person**
Farzad Sarshivi
**Position**
Assisstant Professor
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Anesthesiology
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## Person responsible for updating data

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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