Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Determination of the effect of intravenous dexamethasone during anesthesia and analgesia of axillary block in upper limb fracture surgery

Protocol summary

Study aim
Determination of the effect of intravenous dexamethasone during anesthesia and analgesia of axillary block in upper limb fracture surgery in patients referred to Shahid Rajaei Hospital in Qazvin

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 88 patients. Balanced Block Randomization was used for randomization.

Settings and conduct
Background for determining the effect of intravenous dexamethasone during anesthesia and analgesia of axillary block in orthopedic surgery. Location of Shahid Rajaei Hospital in Qazvin. The researcher, patient, surgeon, nurse, and data analyzer were blinded to the type of group the patient was in. 88 patients who were candidates for upper limb fracture surgery were divided into control and intervention groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 20-60 years, ASA class I-II, all axillary block candidates due to bone fractures. Exclusion criteria included level of consciousness, drug or alcohol use, history of MAOI, TCA, SSRI, phenothiazines or hypnotics, chronic pain based on history and clinical examination, history of dexamethasone allergy, and Lidocaine, shoulder joint osteoarthritis, a history of uncontrolled diabetes, psychotic illness, and block failure.

Intervention groups
The intervention group will receive 8 mg of intravenous dexamethasone and the control group will receive 2 cc of normal saline. Then 0.02 mg / kg midazolam and 2 micrograms / kg fentanyl will be injected intravenously. After performing the control block, the onset of anesthesia will be examined periodically every 2 minutes by sensation and movement of the patient's limb using the sensation of touch and pain, as well as the movement with the movement instruction.

Main outcome variables
Post operational pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210122050109N1**
Registration date: **2021-02-28, 1399/12/10**
Registration timing: **retrospective**

Last update: **2021-02-28, 1399/12/10**
Update count: **0**
Registration date
2021-02-28, 1399/12/10

Registrant information
Name
Anahita Janbaz
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2021-06-21, 1400/03/31
Actual recruitment start date
2020-06-20, 1399/03/31
Actual recruitment end date
2020-10-22, 1399/08/01

Trial completion date
2020-10-22, 1399/08/01

Scientific title
Determination of the effect of intravenous dexamethasone during anesthesia and analgesia of axillary block in upper limb fracture surgery

Public title
The effect of dexamethasone on postoperative hand fracture pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients candidates for axillary block surgery for upper limb surgery (forearm and hand) due to bone fractures that require plaque patients in the age range of 20 to 60 years

Exclusion criteria:
Level of consciousness disorder (GCS <15) drug or alcohol use history of MAOI, TCA, SSRI, phenothiazines or hypnotics chronic pain based on history and clinical examination history of drug sensitivity Dexamethasone and lidocaine shoulder joint osteoarthritis history of uncontrolled diabetes psychotic disease block failure

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **25**
Actual sample size reached: **27**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random: In this method, first the list of names of all patients will be obtained, then a number will be assigned to each of them and the required number will be selected using a table of random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patient will not be aware of the type of study group in which he is placed, as well as the researcher, patient surgeon, patient care nurse in the operating room, recovery ward and post-surgery ward, as well as data analyzer will not be informed about patient grouping.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
3419759811

Approval date
2020-02-19, 1398/11/30

Ethics committee reference number
IR.QUMS.REC.1398.345

Health conditions studied

1

Description of health condition studied
Fracture of forearm

ICD-10 code
S52

ICD-10 code description
Fracture of forearm

Primary outcomes

1

Description
Post operational Pain

Timepoint
Recovery and 1, 2, 4, 6, 12 and 24 hours after receiving the drug

Method of measurement
Numerical Pain Rating Scale

2

Description
Amount of narcotic drug consumption

Timepoint
Post operation

Method of measurement
Patient Document

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 8 mg dexamethasone intravenously in the relevant box and then 0.02 mg / kg midazolam and 2 micrograms / kg fentanyl will be injected intravenously. Then, while the patient is in the supine and arm position in the 90-degree abduction position and the elbow is in the 90-degree flexion position, after filling the position with alcohol and betadine and numbing the skin and subcutaneous tissue with 2 cc of 1% lidocaine by 25G needle, with ultrasound guide and linear probe that is transversely located at the intersection of pectoral and biceps muscles in the proximal inner part of the arm Guide around the arteries seen hypercoa and around each nerve 10 cc of the contents of the 20 cc syringes in the box of the same group will be slowly injected (median nerve in the upper and inner part of the artery and ulnar nerve in the part Upper and external artery and radial nerve in the lower part of the artery).

Category

Treatment - Drugs

2

Description

Control group: The control group will receive 2 cc of normal saline (placebo) in the box instead of dexamethasone.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaei Educational Hospital - Qazvin University of Medical Sciences

Full name of responsible person
Dr. Anahita Janbaz

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Shahid Rajaei Educational Hospital, Qazvin, Iran

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Sponsors / Funding sources

1

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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
Qazvin University of Medical Sciences

Proportion provided by this source
5

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
Qazvin University of Medical Sciences

Full name of responsible person
Anahita Janbaz

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Data on primary and secondary outcomes can be published.
When the data will become available and for how long
One year after the results are published
To whom data/document is available
Researchers and industry owners
Under which criteria data/document could be used
Use the results for further planning and research
From where data/document is obtainable
Alizadeh25@yahoo.com
What processes are involved for a request to access data/document
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Comments