

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison the Effect of Ketamine-Lidocaine and Fentanyl-Lidocaine on Postoperative Analgesia in Axillary Block with Ultrasound Guide in upper Limb Fractures

Protocol summary

Study aim

Comparison the effect of ketamine-lidocaine and fentanyl-lidocaine on postoperative analgesia in axillary block with Ultrasound Guide in upper limb fractures

Design

The study is design as a randomised, controlled, parallel group trial with double blinded outcome assessment. Randomisation was centralised based on randomized block randomization method.

Settings and conduct

Sixty patients candidate of orthopedic surgery of forearm and hand fractures in age group 18 to 75 years are randomly divided into intervention (1) and (2) group. Using an ultrasound device, the neural network is identified and a sterile needle with ultrasound-guided is imported in the axillary space, then medication is injected around the neural network. Pinprick test and three-point scale test are used to evaluate the sensory and motor block of the median, ulnar, radial and musculocutaneous nerves.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients under orthopedic surgery of forearm and hand fractures in age group 18 to 75 years and ASA Class I , II; The exclusion criteria are allergic reaction to drugs used in the study, patients with anemia or bleeding disorders, infection of block location, nerve damage of the limb caused by trauma, neuropathy and addiction to narcotics.

Intervention groups

In the Intervention group (1), patients are received 4mg/kg lidocaine 1% and 50mcg fentanyl during axillary block and in the intervention group (2), patients are received 4mg/kg lidocaine 1% and 30 mg ketamine during axillary block.

Main outcome variables

The time of completion of the sensory and motor block are recorded every 15 minutes after the patient enters

the recovery room. Postoperative pain in 0, 1, 2, 4, 8, 16 and 24 hours after surgery, the first time of request for narcotic and the amount of narcotic consumption after surgery are measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181220042064N1**

Registration date: **2019-02-25, 1397/12/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-25, 1397/12/06**

Update count: **0**

Registration date

2019-02-25, 1397/12/06

Registrant information

Name

Bahram Mohammad Tasbihi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the Effect of Ketamine-Lidocaine and Fentanyl-Lidocain on Postoperative Analgesia in Axillary Block with Ultrasound Guide in upper Limb Fractures

Public title
The Effect of Ketamine-Lidocaine and Fentanyl-Lidocain on Postoperative Analgesia in Axillary Block with Ultrasound Guide in upper Limb Fractures

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients under orthopedic surgery of forearm and hand fractures Age group 18 to 75 years American Society of Anesthesiologists (ASA) classification I , II
Exclusion criteria:
Allergic reaction to drugs used in the study Patients with anemia or bleeding disorders Infection of block location Nerve damage of the limb caused by trauma Neuropathy and addiction to narcotics Patient dissatisfaction

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are randomly divided into two groups based on randomized block randomization method. Randomized blocks are used for this purpose. A random sample based on this method from Sealedenvelope.com has been extracted.

Blinding (investigator's opinion)
Double blinded

Blinding description
Surgeon, responsible for collecting data and data analyzer are unaware of the grouping of patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

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Ahvaz

Province

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Postal code

6135715794

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.AJUMS.REC.1397.023

Health conditions studied

1

Description of health condition studied

Fracture of upper limb

ICD-10 code

T10

ICD-10 code description

Fracture of upper limb, level unspecified

Primary outcomes

1

Description

Postoperative pain

Timepoint

0 (immediately after admission to recovery room), 1, 2, 4, 8, 16 and 24 hours after the completion of the surgical operation

Method of measurement

Visual Analogue Scale (VAS)

2

Description

The time of completion of the sensory block

Timepoint

Every 15 minutes after the patient enters the recovery room

Method of measurement

Pinprick test

3

Description

The time of completion of the motor block

Timepoint

Every 15 minutes after the patient enters the recovery

room
Method of measurement
Three-point scale test

4

Description
The first time of request for narcotic after surgery
Timepoint
From entering the patient to the recovery room for up to 24 hours after surgery
Method of measurement
According to hour

5

Description
The amount of narcotic consumption after surgery
Timepoint
From entering the patient to the recovery room for up to 24 hours after surgery
Method of measurement
The dose of pethidine (mg/kg)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (1): Patients are received 4 mg/kg lidocaine 1% and 50 mcg fentanyl during axillary block.
Category
Treatment - Drugs

2

Description
Intervention group (2): Patients are received 4 mg/kg lidocaine 1% and 30 mg ketamine during axillary block.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
PAIN-9701
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
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Full name of responsible person
Bahram Mohamad Tasbihi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available