Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison the Effect of Ketamine-Lidocaine and Fentanyl-Lidocain 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-lidocain 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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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

Reza Akhondzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Ahvaz University of Medical Sciences

Full name of responsible person

Bahram Mohamad Tasbihi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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