

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the effect of Ketamine and Dexamethasone in combination with Lidocaine on the onset and duration of Axillary block in soft tissue surgery of forearm and hand

Protocol summary

Summary

The purpose of the study : Comparison of the effect of Ketamine and Dexamethasone in combination with Lidocaine on the onset and duration of Axillary block in soft tissue surgery of forearm and hand. Method: Double blind randomized clinical trial. Sample size: 78. Inclusion criteria: Consent to participate in research project and cooperation for axillary block; No addiction to opium, Benzodiazepine, Clonidine; Absence of liver and kidney failure, diabetes, cardiovascular and lung diseases, coagulopathy; Lack of any allergic history to local anesthetics; No use of opium in the past 48 hours; Absence of anatomical deformity or burning or infection in block region; No pregnancy in female patients. Exclusion criteria: The unwillingness or lack of cooperation from the patient during surgery. Study groups: 1) Group receiving lidocaine + Ketamine 2) Group receiving lidocaine +Dexamethasone 3) Group receiving lidocaine. Measurement and recording of variables: 1) Measuring onset of sensory and motor block every three minutes to complete the block and recording it 2) Measuring and Recording duration of sensory and motor block after the completion of surgery every three minutes. Data analysis: Data will be analyzed with statistical tests by using SPSS software, version 22.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030132837N1**
Registration date: **2017-04-20, 1396/01/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-20, 1396/01/31

Registrant information

Name

Behrooz Zaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 7272

Email address

zaman.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran university of medical sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-04-04, 1396/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Ketamine and Dexamethasone in combination with Lidocaine on the onset and duration of Axillary block in soft tissue surgery of forearm and hand

Public title

Comparison of the effect of Ketamine and Dexamethasone in combination with Lidocaine on the onset and duration of Axillary block in soft tissue surgery

of forearm and hand

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Consent to participate in research project and cooperation for axillary block; No addiction to opium, Benzodiazepine, Clonidine; Absence of liver and kidney failure, diabetes, cardiovascular and lung diseases, coagulopathy; Lack of any allergic history to local anesthetics; No use of opium in the past 48 hours; Absence of anatomical deformity or burning or infection in block region; No pregnancy in female patients.

Exclusion criteria: The unwillingness or lack of cooperation from the patient during surgery.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences Ethics Committee

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Postal code

1449614535

Approval date

2016-04-05, 1395/01/17

Ethics committee reference number

IR.IUMS.REC.1394.9211174004

Health conditions studied

1

Description of health condition studied

Soft tissue injury of forearm and hand

ICD-10 code

S50, S51,

ICD-10 code description

Superficial injury of forearm, Open wound of forearm, Injury of nerves at forearm level, Injury of blood vessels at forearm level, Injury of muscle and tendon at forearm level, Superficial injury of wrist and hand, Open wound of wrist and hand, Injury of

Primary outcomes

1

Description

Onset of sensory block

Timepoint

every 3 minutes

Method of measurement

Measuring the length of time between the last injection until complete disappearance of any sense of touch with the stopwatch

2

Description

onset of motor block

Timepoint

every 3 minutes

Method of measurement

Measuring the length of time between the last injection to complete motor paralysis with Stopwatch

3

Description

Duration of sensory block

Timepoint

every 3 minutes

Method of measurement

Measuring the time between onset of complete sensory block until the complete return again sense organs with Stopwatch

4

Description

duration of motor block

Timepoint

every 3 minutes

Method of measurement

Measuring the time between onset of complete paralysis to return of complete movement power with stopwatch

Secondary outcomes

1

Description

Diastolic blood pressure

Timepoint

0, 5, 10, 15, 20, 25 minutes after Axillary block

Method of measurement

Non-invasive automatic sphygmomanometer

2**Description**

Systolic blood pressure

Timepoint

0, 5, 10, 15, 20, 25 minutes after Axillary block

Method of measurement

Non-invasive automatic sphygmomanometer

3**Description**

Pulse rate

Timepoint

0, 5, 10, 15, 20, 25 minutes after Axillary block

Method of measurement

ECG monitoring

4**Description**

Nystagmus

Timepoint

0, 5, 10, 15, 20, 25 minutes after Axillary block

Method of measurement

Find the rapid movements of the eyes of horizontal reciprocating

Intervention groups**1****Description**

The intervention group 1 : Axillary block with 38 cc lidocaine 1% in combination with dexamethasone 8 mg in 2 ml

Category

Other

2**Description**

The intervention group 2 : Axillary block with 38 cc Lidocaine 1% combination with 50 mg of Ketamine in 2 cc

Category

Other

3**Description**

Control group : Axillary block with 38 cc lidocaine 1% in combination with 2 mL of saline

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat Fatemeh Hospital

Full name of responsible person

Siavash Hojjati Ashrafi

Street address

23 St, Asad abadi St, Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Iran university of medical sciences

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Iran university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Hazrat Fatemeh Hospital

Full name of responsible person

Dr Behrooz Zaman

Position

Anesthesiologist / Assistant Professor of Iran University of Medical Sciences

Other areas of specialty/work**Street address**

23 St, Asad abadi St, Tehran

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 0099

Fax**Email**

behroozzaman@gmail.com zaman.b@iums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hazrat Fatemeh Hospital

Full name of responsible person

Dr Behrooz Zaman

Position

Anesthesiologist/ Assistant Professor of Iran

University of Medical Sciences

Other areas of specialty/work**Street address**

23 St, Asad abadi St, Tehran

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 0099

Fax**Email**

behroozzaman@gmail.com zaman.b@iums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Hazrat Fatemeh Hospital

Full name of responsible person

Dr Behrooz Zaman

Position

Anesthesiologist / Assistant Professor of Iran

University of Medical Sciences

Other areas of specialty/work**Street address**

23 St, Asad abadi St, Tehran

City

Tehran

Postal code

1433933111

Phone

+98 21 8871 0099

Fax**Email**

behroozzaman@gmail.com zaman.b@iums.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty