

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Investigating the preventive effect of lidocaine infusion and ketamine infusion on pain after upper limb orthopedic surgery under general anesthesia

Protocol summary

Study aim

Determining and comparing the preventive effect of lidocaine and ketamine on pain after upper limb orthopedic surgery

Design

A randomized, triple-blinding clinical trial, with parallel groups, Phase 3 on 180 patients

Settings and conduct

In this three-blind randomized clinical trial study, 180 eligible patients referred to Al-Zahra and Kashani Hospital in Isfahan will be included in the study and will be randomly divided into three groups. At the end of the surgery, patients are injected with lidocaine or ketamine or normal saline. Then the bleeding rate, hemodynamic parameters, and complications after surgery will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria include patients who are candidates for elective upper extremity orthopedic surgery under general anesthesia, aged 65-18 years, and have informed consent to participate in this study. Exclusion criteria include addiction to opioid products, having an underlying disease (hypertension and uncontrolled diabetes or any neurological disorder) that has led to impaired sensation or movement of the operated organ, and sensitivity to lidocaine or ketamine.

Intervention groups

The first intervention group: patients in this group will be injected with lidocaine infusion at a low dose (1 mg/kg/hour) at the end of the operation. The second intervention group: patients in this group, at the end of the operation, are given intravenous ketamine infusion at a dose (0.25 mg per kilogram of body). Control group: patients in this group will be injected with normal saline infusion.

Main outcome variables

Pain; Mean arterial pressure; Heart beat; Oxygen

saturation (SPO2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N68**

Registration date: **2023-06-14, 1402/03/24**

Registration timing: **prospective**

Last update: **2023-06-14, 1402/03/24**

Update count: **0**

Registration date

2023-06-14, 1402/03/24

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the preventive effect of lidocaine infusion and ketamine infusion on pain after upper limb orthopedic surgery under general anesthesia

Public title

The effect of lidocaine and ketamine on pain after upper limb orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients for elective upper extremity orthopedic surgery under general anesthesia Age 65-18 years Informed consent to participate in this study

Exclusion criteria:

Addiction to opioid products Having an underlying disease (hypertension and uncontrolled diabetes or any neurological disorder) that has led to impaired sensation or movement of the operated organ Hypersensitivity to lidocaine or ketamine

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 180 eligible patients are randomly selected. Then the letters A, B and C are written on 60 sheets and each one is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to achieve the triple-blind study, two drugs lidocaine and ketamine as well as placebo will be prepared daily by the operating room nurse (without the knowledge of the researcher) in the same syringes and labeled as A, B, C, and D. And is given daily to the anesthesiologist (researcher). Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Azadi Square.

City

Isfaha

Province

Isfahan

Postal code

8174673461

Approval date

2022-10-26, 1401/08/04

Ethics committee reference number

IR.MUI.MED.REC.1401.275

Health conditions studied**1****Description of health condition studied**

Upper extremity orthopedic surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mean arterial pressure

Timepoint

In the basic times, the first hour every 15 minutes, the second hour every 30 minutes, the next 4 hours every 1 hour and after that every 2 hours for 24 hours.

Method of measurement

Monitoring device

2**Description**

Heart beat

Timepoint

In the basic times, the first hour every 15 minutes, the second hour every 30 minutes, the next 4 hours every 1 hour and after that every 2 hours for 24 hours.

Method of measurement

Monitoring device

3

Description

Oxygen saturation percentage (SPO2)

Timepoint

In the basic times, the first hour every 15 minutes, the second hour every 30 minutes, the next 4 hours every 1 hour and after that every 2 hours for 24 hours.

Method of measurement

Monitoring device

4

Description

Pain

Timepoint

In the basic times, the first hour every 15 minutes, the second hour every 30 minutes, the next 4 hours every 1 hour and after that every 2 hours for 24 hours.

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: patients in this group will be injected with lidocaine infusion at a low dose (1 mg/kg/hour) at the end of the operation.

Category

Treatment - Drugs

2

Description

Second intervention group: patients in this group, at the end of the operation, are given intravenous ketamine infusion at a dose (0.25 mg per kilogram of body).

Category

Treatment - Drugs

3

Description

Control group: patients in this group will be injected with normal saline infusion.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Alireza Hoghooghi

Street address

Soffe Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alireza.hoghooghi@gmail.com

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Alireza Hoghooghi

Street address

Kashani street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

alireza.hoghooghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences and Health Services, Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Alireza Hoghooghi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alireza.hoghooghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Alireza Hoghooghi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alireza.hoghooghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Marzieh Mahdi Zadeh
Position
Non-faculty specialist doctor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Fax
Email
marmi.mhd1376@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available