Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 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)

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+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
Isfehan

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
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Postal code
8174675731
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2

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
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Kashani street, Isfahan
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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
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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

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Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

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Specialist

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Person responsible for updating data

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Name of organization / entity
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Position
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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