Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparative study of intravenous administration of low-dose Propofol with lidocaine on the reduction of local pain caused by intravenous injection of full-dose Propofol during induction of general anesthesia

Protocol summary

Study aim

Comparison of low-dose intravenous of Propofol and Lidocaine on the reduction of local pain caused by intravenous injection of full-dose Propofol during anesthesia induction.

Design

This randomized, double-blind, parallel-group, phase 2-3 clinical trial will be conducted on 88 patients 18 to 60 years who are candidates for elective surgery under general anesthesia using a block randomization.

Settings and conduct

In operating room, after fixing a 20G angiocatheter in the veins on the back of the patient's hand, the hand is held up for 10 seconds and a tourniquet is tied at the top of the angiocatheter and one of two drugs, propofol and lidocaine, is injected in syringes of the same volume and shape. After 2 minutes, the vein is opened and 0.5 mg/kg propofol is injected and the intensity of hand 's pain is recorded based on the VAS. Then the rest of the propofol (1.5 mg/kg) is injected along with the other induction drugs, and the patient is then intubated.

Participants/Inclusion and exclusion criteria

Inclusion:18-60 years; ASA class1&2; Elective surgery under general anesthesia.Exclusion: Cardiovascular disease; Seizures;Use of narcotics and sedatives; Food and drug allergies; Infection or wounds on the back of the hands.

Intervention groups

In operating room, after fixing a 20G angiocatheter in the veins on the back of the patient's hand, the hand is held up for 10 seconds and a tourniquet is tied at the top of the angiocatheter. Then, one of the two drugs, lidocaine (40 mg) or propofol (20 mg), is injected. After 2 minutes, the vein is opened and 0.5 mg/kg propofol is injected. Then, the intensity of pain in the patient's hand during the injection of propofol is recorded based on the VAS. Finally, anesthesia is induced by injecting the rest of the propofol (1.5 mg/kg) and the other drugs, and intubation will be performed after 3 minutes.

Main outcome variables

Intensity of hand pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N28**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date

2026-07-20, 1405/04/29

Registrant information

Name

Nahid Manuchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2027-07-23, 1406/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of intravenous administration of low-dose Propofol with lidocaine on the reduction of local pain caused by intravenous injection of full-dose Propofol during induction of general anesthesia

Public title
Post injection Propofol pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged from 18 to 60 years old ASA class 1 and 2 Candidate for elective surgery under general anesthesia
Exclusion criteria:
History of cardiovascular disease History of seizure Consumption history of narcotics, sedatives and anti anxiety drugs Previous allergy to egg and peanut Previous allergy to Propofol and lidocaine Infection or wound on dorsal of hand
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the quadruple Block Randomization method. For this purpose, we prepare four sheets of paper.Write the letter A on two sheets and the letter B on the other two sheets. Mix the sheets together and place them in the desk drawer. With the referral of each eligible patient, one of the sheets is randomly taken out and based on this sheet is A or B, it will be assigned to one of the two groups of Propofol or Lidocaine. After randomly pulling out all four sheets, all the papers are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
After inserting a size 20 angiocatheter into the patient's hand and receiving 5ml/kg of Ringer's solution, the patient's hand will be held up for 10 seconds, then the top of the angiocatheter will be blocked with a tourniquet, and on the randomization block, one of two drugs, Lidocaine (40 mg) or Propofol (20 mg), will be injected by the anesthesiologist. in syringes of the same shape and volume, covered with cloth tape, and numbered by the nurse anesthetist (who is unaware of the details of the design).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Mahdieh Street, Hamadan University of Medical Sciences
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Postal code
6517838678
Approval date
2026-04-25, 1405/02/05
Ethics committee reference number
IR.UMSHA.REC.1405.052

Health conditions studied

1

Description of health condition studied
Pain reduction from intravenous injection of full dose of propofol
ICD-10 code
Y48.1
ICD-10 code description
Drugs, medicaments and biological substances causing adverse effects in therapeutic use

Primary outcomes

1

Description
Local Pain Score
Timepoint
After injection of 1/4 of Propofol dose
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Systolic & Diastolic Blood Pressure
Timepoint
Before and after injection of 1/4 dose of propofol, After injection of full dose of propofol and before & after intubation
Method of measurement
Automatic non-invasive blood pressure monitor

2

Description
Mean Arterial Pressure
Timepoint
Before and after injection of 1/4 dose of propofol, After injection of full dose of propofol and before & after intubation
Method of measurement
Automatic non-invasive blood pressure monitor

3

Description
Heart rate
Timepoint
Before and after injection of 1/4 dose of propofol, After injection of full dose of propofol and before & after intubation
Method of measurement
Pulse Oximetry

4

Description
Amount of ephedrine and atropine used
Timepoint
During the operation
Method of measurement
Milligram

Intervention groups

1

Description
Intervention group: After entering the operating room, a 20-gauge angiocatheter is first fixed in the veins on the back of the patient's hand. After receiving 5 ml/kg of Ringer's serum, the patient's hand is held up for 10 seconds and then the upper part of the angiocatheter is blocked with a tourniquet, and then lidocaine (40 mg) is injected by the anesthesiologist through the same angiocatheter. After 2 minutes, the vein is opened and ¼ of the induction dose of propofol (0.5 mg/kg) is injected by the anesthesiologist through the same vein. Then, the intensity of pain in the patient's hand during the injection of propofol is assessed based on the visual scale of pain(VAS) and recorded in a questionnaire. Then, anesthesia induction is completely performed by injecting 2 ug/kg of fentanyl and the remaining dose of propofol (1.5 mg/kg) and 0.5 mg/kg of atracurium, and after 3 minutes, intubation will be performed.
Category
Treatment - Drugs

2

Description
Intervention group: After entering the operating room, a 20-gauge angiocatheter is first fixed in the veins on the back of the patient's hand. After receiving 5 ml/kg of Ringer's serum, the patient's hand is held up for 10 seconds and then the upper part of the angiocatheter is blocked with a tourniquet, and then propofol (20 mg) is injected by the anesthesiologist through the same angiocatheter. After 2 minutes, the vein is opened and ¼ of the induction dose of propofol (0.5 mg/kg) is injected by the anesthesiologist through the same vein. Then, the intensity of pain in the patient's hand during the injection of propofol is assessed based on the visual scale of pain(VAS) and recorded in a questionnaire. Then, anesthesia induction is completely performed by injecting 2 ug/kg of fentanyl and the remaining dose of propofol (1.5 mg/kg) and atracurium 0.5 mg/kg, and intubation will be performed after 3 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Nahid Manouchehrian
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Sponsors / Funding sources

1

Sponsor
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Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Nahid Manouchehrian

Position
Professor of Hamadan university of medical sciences

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Latest degree
Specialist

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Person responsible for updating data

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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