Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effects of Ketorolac and Lidocaine on Reducing Pain During Propofol IV Injection in general anesthesia induction with or without tourniquet

Protocol summary

Study aim

Comparison of the Effects of Ketorolac and Lidocaine on Reducing Pain During Propofol IV Injection in general anesthesia induction with or without tourniquet by Considering the contextual variables , Kosar hospital , Semnan ,2021

Design

Clinical trial, with parallel groups, not blinded, randomized, phase 3 on 120 patients, quadruple permutation block was used for randomization

Settings and conduct

120 patients in Kosar Hospital of Semnan in 1400 is randomly divided into 4 groups. In L1, after injecting 40 mg of lidocaine, wait 30 seconds and inject a quarter of Propofol. In L2, after using the tourniquet, inject Lidocaine, and after 30 seconds, release the tourniquet and immediately inject a quarter of Propofol. In K1, after injecting 10 mg of Ketorolac, we follow L1. In K2, after using the tourniquet, Ketorolac is injected and we act according to L2 group. Finally, pain intensity is assessed based on verbal scoring (VRS) criteria.

Participants/Inclusion and exclusion criteria

Patients with ASA 1 and 2 who have no history of drug, analgesic, or alcohol dependence and are not allergic to Propofol, Lidocaine, and Ketorolac, or who do not have chronic pain syndromes, neurological or psychological disease are eligible for the study. Patients should be able to communicate verbally and not be pregnant.

Intervention groups

L1: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 40 mg Lidocaine L2: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 40 mg Lidocaine with tourniquet K1: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg Ketorolac K2: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg Ketorolac with tourniquet

Main outcome variables

The severity of immediate pain is assessed based on VRS. Painless (0) Mild pain (1) Moderate pain (2) Severe pain (3)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211101052931N1**
Registration date: **2021-12-02, 1400/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-02, 1400/09/11**
Update count: **0**

Registration date

2021-12-02, 1400/09/11

Registrant information

Name

Farzaneh Bahmani Motlagh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Ketorolac and Lidocaine on Reducing Pain During Propofol IV Injection in general anesthesia induction with or without tourniquet

Public title

Comparison of the Effects of Ketorolac and Lidocaine on Reducing Pain of Propofol with or without tourniquet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients must be in the American Society of Anesthesiology or ASA Class 1 and 2 . Have the ability to communicate verbally.

Exclusion criteria:

People who are pregnant. Patients with a history of hypnotic, narcotic, or analgesic use in the 24 hours before the surgery or have a history of drug, analgesic, or alcohol dependence Patients who are prohibited from taking Propofol (including allergies to foods such as eggs, soybeans, and Propofol), prohibition of lidocaine or ketorolac, or other nonsteroidal anti-inflammatory drugs (NSAIDs). Patients with chronic pain syndromes, neurological or psychological diseases. Patients who become allergic to drugs during the test.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (quadruple blocks) All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 30 blocks to select 120 people. We randomly select these blocks from the numbers 1 to 6.Using R software, we choose a random number between the numbers 1 to 6. For example, number 6 is chosen as the first block and number 2 as the forth block. The people who enter the study are given B-A-A-BA- A-B-B, respectively. Finally, group 1 and group 2 will be identified

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences - Research and development Vice

Street address

Semnan University of Medical Sciences

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.SEMUMS.REC.1400.185

Health conditions studied

1

Description of health condition studied

Each patient is a candidate for elective surgery who uses Propofol for anesthesia.(Comparison of the Effects of Ketorolac and Lidocaine on Reducing Pain During Propofol IV Injection with or without tourniquet in general anesthesia induction)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in VRS questionnaire

Timepoint

Immediately after intravenous injection of a quarter of Propofol in induction of anesthesia

Method of measurement

Pain intensity is assessed according to the Verbal Rating Scale(VRS)

Secondary outcomes

empty

Intervention groups

1

Description
L1: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 40 mg Lidocaine
Category
Treatment - Drugs

2

Description
L2: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 40 mg Lidocaine with tourniquet
Category
Treatment - Drugs

3

Description
K1: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg Ketorolac
Category
Treatment - Drugs

4

Description
K2: Injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg Ketorolac with tourniquet
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital in Semnan
Full name of responsible person
Farzaneh Bahmani Motlagh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
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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
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Abolfazl Abdollahpoor
Position
Medical Extern
Latest degree
A Level or less
Other areas of specialty/work
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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