

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)

Phone

+98 21 7746 8625

Email address

f.bahmani.98@gmail.com

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

Street address

Kosar Hospital in Semnan

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3344 1022

Fax

+98 23 3343 7837

Email

kosarhos@semums.ac.ir

Web page address

http://semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Koukhaei

Street address

Semnan University of Medical Sciences

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3344 1022

Fax

+98 23 3343 7837

Email

kosarhos@semums.ac.ir

Web page address

http://semums.ac.ir

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

Anesthesiology

Street address

Semnan University of Medical Sciences

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3344 1022

Fax
+98 23 3343 7837
Email
kosarhos@semums.ac.ir
Web page address
<http://semums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Abolfazl Abdollahpoor
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Semnan University Of Medical Sciences
City
Semnan
Province
Semnan
Postal code
3519899951
Phone
+98 23 3344 1022
Fax
+98 23 3343 7837
Email
felordce@yahoo.com
Web page address
<http://semums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Abolfazl Abdollahpoor

Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Semnan University of Medical Sciences
City
Semnan
Province
Semnan
Postal code
3519899951
Phone
+98 23 3344 1022
Fax
+98 23 3343 7837
Email
kosarhos@semums.ac.ir
Web page address
<http://semums.ac.ir>

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