

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effects of Ketorolac, Metoclopramide, Lidocaine on Reducing Pain During Propofol IV Injection in general anesthesia induction

Protocol summary

Study aim

Comparison of the Effects of Ketorolac, Metoclopramide, Lidocaine on Reducing Pain During Propofol IV Injection

Design

randomized double blinded clinical trial with control and parallel groups

Settings and conduct

In this study 120 patients are randomly divided into four groups. Before anesthesia induction, 2 cc water is injected to group A, 40 mg Lidocaine is injected to group L, 10 mg Metoclopramide is injected to group M and 30 mg Ketorolac is injected to group K intravenously; which is followed by IV injection of 30 mg propofol at rate of 0.5 cc per min to all four groups. Immediately after propofol injection and before complete anesthesia, pain severity is recorded by operating room technician according to verbal rating score (VRS) as following: without pain (0), mild: the pain which is expressed verbally with no grimacing (1), moderate: the pain which is expressed by grimacing (2), severe: the pain which is accompanied by screaming or arm withdrawal (3) Then the rest of Propofol is injected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 18-50 years old who candidates for elective operation . Exclusion criteria: any history of sedative, narcotic or analgesic agent use during 24 hours before surgery, any history of narcotic or analgesic drug or alcohol abuse, any contraindication of Propofol, Lidocaine, Ketorolac or other NSAIDs use, chronic pain syndromes, past history of neurologic or psychiatric disorders, pregnancy, inability to communicate verbally.

Intervention groups

Group A: IV injection of Propofol after water Group L: IV injection of Propofol after Lidocaine Group M: IV injection of Propofol after Metoclopramide Group K: IV injection of Propofol after Ketorolac

Main outcome variables

pain severity, intervention, age, sex, BMI, ASA, comorbidities, smoking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150417021806N5**

Registration date: **2020-08-30, 1399/06/09**

Registration timing: **retrospective**

Last update: **2020-08-30, 1399/06/09**

Update count: **0**

Registration date

2020-08-30, 1399/06/09

Registrant information

Name

Abolfazl Abdollahpoor

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2020-02-20, 1398/12/01

Trial completion date

2020-02-20, 1398/12/01

Scientific title

Comparison of the Effects of Ketorolac, Metoclopramide, Lidocaine on Reducing Pain During Propofol IV Injection in general anesthesia induction

Public title

Effects of Ketorolac, Metoclopramide, Lidocaine on Reducing Pain During Propofol IV Injection

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patient 18-50 year old who candidate for elective surgery with ASA1 and ASA2

Exclusion criteria:

sedative , analgesic or narcotic agents consumption within 24 hours before surgery analgesic or narcotic drugs or alcohol abuse contraindications of lidocain, metochlopramide, ketorolac or other NSAIDs contraindications of propofol including allerlic reaction to foods such as egg or soy bean chronic pain disorders neurologic or psychiatric disorders pregnancy unable to communicate verbally

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

We use classified quadratic permutation block to randomize the patients. All the patients are divided into 4 groups including men 18to34 years old, women 18to34 years old, men 35to50 years old and women 35to50 years old. Then blocked randomization is applied to each group separately.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding is applied to both patients and anesthesiologist who injects drugs and records the pain severity.The anesthesiologist is unaware of the type of the drugs and injects prefilled syringes; then he asks about the severity of pain and records the answers. The patient are unaware of the type of the drug ,too.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Semnan University of Medical Sciences

Street address

Kosar hospital, Amin Blvd, Golestan Town

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Province

Semnan

Postal code

9995135198

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.SEMUMS.REC.1398.190

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

Pain During Propofol IV Injection in general anesthesia induction

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes**1****Description**

Pain During Propofol IV Injection

Timepoint

Immediately after Propofol injection, before complete anesthesia, the severity of pain on injection is recorded.

Method of measurement

Verbal Rating Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: After injection of 2 cc water, 30 milligram

Propofol is injected at the rate of 0.5cc per second

Category
Placebo

2

Description
Intervention group 1: After injection of 40 milligram Lidocain, 30 milligram Propofol is injected at the rate of 0.5cc per second.

Category
Other

3

Description
Intervention group 2: After injection of 10 milligram Metoclopramide, 30 milligram Propofol is injected at the rate of 0.5cc per second.

Category
Other

4

Description
Intervention group 3: After injection of 30 milligram Ketorolac, 30 milligram Propofol is injected at the rate of 0.5cc per second.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar hospital

Full name of responsible person
Abolfazl Abdollahpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Professor Parviz Kokhayee

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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
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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