Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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 devided 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, Lidocain, 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 alleric 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
City
Semnan
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

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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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Specialist

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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