Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

Study aim

Comparison of the Effects of Metoclopramide and Lidocaine on Reducing Pain During Propofol Injection with or without tourniquet ,Semnan ,2021

Design

Clinical trial, with parallel groups, not blinded, randomized, on 120 patients, There are two drugs in total (A B), each in two states with and without tourniquets , These names were introduced to the software and the software was run to assign equal samples to each group.

Settings and conduct

120 patients is randomly divided into 4 groups. L1, after injecting 40 mg of lidocaine, wait 30 seconds and inject a quarter of Propofol. L2, after using the tourniquet, inject Lidocaine, and after 30 seconds, release the tourniquet and immediately inject a quarter of Propofol. M1, after injecting 10 mg of metoclopramide, we follow L1. M2, after using the tourniquet, metoclopramide is injected and we act according to L2 group. Finally, pain intensity is assessed based on (VRS) criteria.

Participants/Inclusion and exclusion criteria

Candidates for elective surgery who require general anesthesia. Eligible for ASA 1 and 2 who have no history of drug, analgesic and are not allergic to propofol, lidocaine, and metoclopramide, or who have chronic pain syndromes, neurological disease, or psychiatry. have. 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 by using the tourniquet M1: injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg metoclopramide M2: injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg metoclopramide by using the tourniquet

Main outcome variables

The severity of immediate pain on VRS. (0) (1) (2) (3)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211101052932N1**
Registration date: **2022-02-12, 1400/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-12, 1400/11/23**
Update count: **0**

Registration date

2022-02-12, 1400/11/23

Registrant information

Name

parinaz mirakhorli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3334 5917

Email address

parinaz.mir1997@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 Metoclopramide and Lidocaine on Reducing Pain During Propofol IV Injection in general anesthesia induction with or without tourniquet , Kosar hospital , Semnan ,2021

Public title

Comparison of the Effects of Metoclopramide 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. All patients undergoing elective surgery who require general anesthesia, regardless of the type of surgery and the individual's disease.

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 metoclopramide, or other nonsteroidal anti-inflammatory drugs (NSAIDs). Patients with chronic pain syndromes, neurological or psychological diseases.

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

There are two drugs in total (A B), each in two states with and without tourniquets (0 and 1), which can be 4 general cases with these names: A0 A1 B0 B1 These names were introduced to the software and the software was run to assign equal samples to each group. The output list of the software will be the criterion for action. https://www.random.org/lists/ For random assignment to 4 groups, the names of each group up to 30 (each item in a row) were entered in the software box and executed in the software. In this way, the software has separate boxes In the first box 30 times A0 In the second box 30 times A1 In the third box 30 times B0 B1 is placed in the fourth box 30 times The software has a key that by hitting it, the software itself randomizes the data

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

no

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

2021-10-26, 1400/08/04

Ethics committee reference number

IR.SEMUMS.REC.1400.184

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 Metoclopramide 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
Group 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
Group L2: injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 40 mg lidocaine by using the tourniquet
Category
Treatment - Drugs

3

Description
M1: injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg Metoclopramide
Category
Treatment - Drugs

4

Description
Group M2: injection of 2 mg / kg Propofol at a rate of 0.5 cc per second after injection of 10 mg metoclopramide by using the tourniquet
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital in Semnan
Full name of responsible person
Parinaz Mirakhorli
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Parviz Koukhaei
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Email
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Web page address
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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 Abdollahpour
Position
Associate professor
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