Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the cold normal saline, lidocaine and metoclopramide and the combination of lidocaine and cold normal saline on pain caused by propofol injection

Protocol summary

Study aim

Comparison of the use of cold serum, lidocaine and metoclopramide and the combination of lidocaine and cold serum on pain caused by propofol injection

Design

In this double-blind clinical trial, 120 patients aged 18-60 years (number of samples based on previous studies) with ASA class 1, 2 who are candidates for elective surgery under general anesthesia are randomly selected. Patients who experience pain at the injection site before the injection of the drug or propofol, or if the patient is anxious or uncooperative or allergic to any of the drugs under study, and patients with a history of seizure disorders, cardiovascular disease And have psychiatric problems will also be excluded from the study.

Settings and conduct

It was performed in Sabzevar city relief hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Need for general anesthesia with propofol injection with consent to participate in evaluation between 18 and 60 years old with ASA class 1 and 2 Exclusion criteria: Reluctance to study Patients under 20 years and over 60 years Patients with ASA grade equal to or greater than 3 Patients with advanced heart and lung problems Sensitivity to any of the drugs used in the study

Intervention groups

Patients are randomly divided into 4 groups of 30 people. Without any anesthetic prodrug, the first group as the control group will be injected with 10 ml of normal saline at room temperature, the second group with 10 ml of 0.5% lidocaine, and the third group with 10 ml of 4 ° C normal saline

Main outcome variables

Age; Gender; Medication; Pain rate; Duration of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170404033202N10**
Registration date: **2022-03-23, 1401/01/03**
Registration timing: **retrospective**

Last update: **2022-03-23, 1401/01/03**
Update count: **0**

Registration date

2022-03-23, 1401/01/03

Registrant information

Name

Atefeh Asadi

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

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the cold normal saline, lidocaine and metoclopramide and the combination of lidocaine and cold normal saline on pain caused by propofol injection

Public title
Comparison of the cold normal saline, lidocaine and metoclopramide and the combination of lidocaine and cold normal saline on pain caused by propofol injection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Need for general anesthesia with propofol injection with consent to participate in evaluation between 18 and 60 years old ASA class 1 and 2

Exclusion criteria:
Reluctance to studyPatients Patients under 20 years and over 60 years Patients with ASA grade equal to or greater than 3 Patients with advanced heart and lung problems Sensitivity to any of the drugs used in the study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be selected at random using the most available people for the study. Each person was given a code A or B at random (sheet or envelope) and treatment was performed based on it (group A was intervention and group B was control).

Blinding (investigator's opinion)
Double blinded

Blinding description
In all groups, the amount of pain at 0, 15, and 30 minutes after propofol injection is assessed by another observer who is unaware of the type of drug being injected, based on the VAS, from zero to 10 (zero painless, 10 severe pain). Outcome assessment is also done by someone who does not know about the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sabzevar Medical Sciences

Street address
Sabzevar Medical Sciences Campus

City
Sabzevar

Province
Razavi Khorasan

Postal code
9613885697

Approval date
2021-10-12, 1400/07/20

Ethics committee reference number
IR.MEDSAB.REC.1400.172

Health conditions studied

1

Description of health condition studied
Reduction of pain caused by propofol in anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Reduction of pain caused by propofol injection after drug injection

Timepoint
Pain rate at 0, 15 and 30 minutes after propofol injection

Method of measurement
Based on VAS from zero to 10

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The case group consisting of four groups including the first group will inject 10 ml of 0.5% lidocaine at room temperature. The tourniquet is emptied 15 seconds after the injection. Propofol 50 mg 1% in a volume of 5 ml is then injected into all three groups within 5 seconds. In all groups, the amount of pain at 0 and 10 minutes after propofol injection was assessed by another observer who was unaware of the type of drug being injected, according to Wang Baker. Induction of anesthesia and intubation is performed with 2 mg midazolam, 1.5□ / kg fentanyl, the remaining dose of propofol (total dose 2.5 mg / kg and 0.6 mg / kg

atracurium. Also, heart rate, mean blood pressure before Drug injection and before induction to evaluate the effect of pain on hemodynamics and immediately after intubation and 5 minutes after intubation to evaluate the effect of lidocaine and propofol on hemodynamics.

Category

Treatment - Drugs

2

Description

Intervention group 2: The second group will inject 10 ml of normal serum cold saline 4 degrees at room temperature. The tourniquet is emptied 15 seconds after the injection. Propofol 50 mg 1% in a volume of 5 ml is then injected into all three groups within 5 seconds. In all groups, the amount of pain at 0 and 10 minutes after propofol injection was assessed by another observer who was unaware of the type of drug being injected, according to Wang Baker. Induction of anesthesia and intubation is performed with 2 mg midazolam, 1.5 / kg fentanyl, the remaining dose of propofol (total dose 2.5 mg / kg and 0.6 mg / kg atracurium. Also, heart rate, mean blood pressure before Drug injection and before induction to evaluate the effect of pain on hemodynamics and immediately after intubation and 5 minutes after intubation to evaluate the effect of lidocaine and propofol on hemodynamics.

Category

Treatment - Drugs

3

Description

Intervention group 3: The third group will inject 10 ml of 0.5% lidocaine with 10 cc of normal saline 4 ° at room temperature. The tourniquet is emptied 15 seconds after the injection. Propofol 50 mg 1% in a volume of 5 ml is then injected into all three groups within 5 seconds. In all groups, the amount of pain at 0 and 10 minutes after propofol injection was assessed by another observer who was unaware of the type of drug being injected, according to Wang Baker. Induction of anesthesia and intubation is performed with 2 mg midazolam, 1.5 / kg fentanyl, the remaining dose of propofol (total dose 2.5 mg / kg and 0.6 mg / kg atracurium. Also, heart rate, mean blood pressure before Drug injection and before induction to evaluate the effect of pain on hemodynamics and immediately after intubation and 5 minutes after intubation to evaluate the effect of lidocaine and propofol on hemodynamics.

Category

Treatment - Drugs

4

Description

Intervention group4: The fourth group will be injected with 10 mg metoclerine pyramid at room temperature. The tourniquet is emptied 15 seconds after the injection. Propofol 50 mg 1% in a volume of 5 ml is then injected into all three groups within 5 seconds. In all groups, the amount of pain at 0 and 10 minutes after propofol injection was assessed by another observer who was unaware of the type of drug being injected, according to Wang Baker. Induction of anesthesia and intubation is performed with 2 mg midazolam, 1.5 / kg fentanyl, the remaining dose of propofol (total dose 2.5 mg / kg and 0.6 mg / kg atracurium. Also, heart rate, mean blood pressure before Drug injection and before induction to evaluate the effect of pain on hemodynamics and immediately after intubation and 5 minutes after intubation to evaluate the effect of lidocaine and propofol on hemodynamics.

Category

Treatment - Drugs

5

Description

Control group: The control group will be injected with 10 ml of normal saline at room temperature. The tourniquet is emptied 15 seconds after the injection. Propofol 50 mg 1% in a volume of 5 ml is then injected into all three groups within 5 seconds. In all groups, the amount of pain at 0 and 10 minutes after propofol injection was assessed by another observer who was unaware of the type of drug being injected, according to Wang Baker. Induction of anesthesia and intubation is performed with 2 mg midazolam, 1.5 / kg fentanyl, the remaining dose of propofol (total dose 2.5 mg / kg and 0.6 mg / kg atracurium. Also, heart rate, mean blood pressure before Drug injection and before induction to evaluate the effect of pain on hemodynamics and immediately after intubation and 5 minutes after intubation to evaluate the effect of lidocaine and propofol on hemodynamics.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Relief Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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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
Sabzevar 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
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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

Not applicable

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