Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative study of prophylactic effect of injectable paracetamol and lidocaine on pain caused by intravenous injection of propofol in children 6 to 10 years

Protocol summary

Study aim

Determining and comparing the prophylactic effect of injectable paracetamol and lidocaine on intravenous propofol injection pain in children 6 to 10 years of age under general anesthesia.

Design

Clinical trial with control group, with parallel group, double-blind, randomized, on 90 patients. For randomization, block generation is used by Excel program.

Settings and conduct

This study will be conducted in pediatrics operation room of Isfahan Imam Hossein Hospital. The anesthesia technician who inject the drugs, the person who collect the data and the analyzer will not be informed about the groups of study. After preparation, one minute before propofol injection, we will inject intravenous Pracetamol in Intervention group 1, and we will inject Lidocaine in group 2 , also we will inject 2 cc normal saline in the control group and after 15 seconds propofol will be injected.

Participants/Inclusion and exclusion criteria

Inclusion criteria include children 6 to 10 years old who are candidates for surgery under general anesthesia with propofol. Exclusion criteria: Known liver; heart;neurological disease and a history of any metabolic disease and any drug reactions and drug allergies.

Intervention groups

Intervention group 1: one minute before Propofol injection, we will inject 1 milligram per kilogram Paractamol intravenously. Intervention group 2: one minute before Propofol injection, we will inject 1 milligram per kilogram Lidocaine intravenously. Control group: one minute before Propofol injection, we will inject 2 cc Normal saline intravenously.

Main outcome variables

Pain score, mean arterial pressure, heart rate and agitation rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210403050824N1**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **prospective**

Last update: **2021-07-11, 1400/04/20**
Update count: **0**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

ahmad Karimi hasan abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4274 3155

Email address

ahmadkarimi1886@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-21, 1400/04/30

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative study of prophylactic effect of injectable paracetamol and lidocaine on pain caused by intravenous injection of propofol in children 6 to 10 years

Public title
paracetamol and lidocaine in pain of intravenous propofol

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Children 6 to 10 years general anesthesia with propofol ASA1,ASA2

Exclusion criteria:
Known liver disease Known heart disease Known neurological disease History of metabolic disease Drug reactions and allergies

Age
From **6 years** old to **10 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sequence (blocking) is generated by the help of Excel software and blocks of six are used to equalize the three groups so that the intervention groups 1 and 2 or the control of each person included in the study, can be determined randomly and equally. The blocks of six are separated from the samples and placed in the block randomly by the Excel software of group A or B or C. At the end, it is determined which letter represents the intervention group 1 and 2 and which is for the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs are prepared by someone outside the research team in the operating room. He equalize their volumes in ready-made syringes with a coating so that its contents are not known. Group codes are then written on the syringes. The anesthetist who inject the drug and the anesthesiologist who collect the data do not know the group's codes. Patients are also unaware of group assignments. The person who is doing the statistical analysis also does not know how the codes have been assigned to the study groups. After completing the analysis, the codes will be opened.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Science., Hezar Jarib Ave., Azadi Sq., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-10-17, 1399/07/26

Ethics committee reference number
IR.MUI.MED.REC.1399.634

Health conditions studied

1

Description of health condition studied
Pain induced by intravenous propofol injection.

ICD-10 code
T88.5

ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description
Patient pain score at baseline and one minute after propofol injection.

Timepoint
At baseline when injecting propofol and one minute after injecting propofol

Method of measurement
Propofol injection pain score based on the patient's motor and verbal response

2

Description
Heart rate at baseline and one minute after propofol administration.

Timepoint
At baseline and one minute after propofol injection

Method of measurement
Saadat Standard monitoring

3

Description
Mean arterial pressure at baseline and one minute after propofol injection.
Timepoint
At baseline and one minute after propofol injection
Method of measurement
Saadat Standard monitoring

4

Description
Patient agitation during propofol injection.
Timepoint
At baseline and one minute after propofol injection
Method of measurement
Richmond Agitation scale

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: All patients have been taken to the operating room then after premedication with 0.1 milligram per kilogram of midazolam, intravenous cannula number 20 have been inserted in non-dominant dorsal veins and 10 cc per kilogram of Ringer's lactate serum will be infused . Then the arm will be held higher than body for one minute to drain the blood. The cuff of the sphygmomanometer will be closed on the same arm and inflates up to 20 mmHg above systolic blood pressure. Then 1 milligram per kilogram of Paracetamol will be injected intravenously and the cuff will be emptied after one minute. Finally 2 milligram per kilogram of Propofol is then injected over 15 seconds. During the intervention we will record the patient's vital signs, Heart Rate, Blood Pressure, and movements and speech rate one minute before injection of Propofol and in the first minute after injection in a questionnaire.
Category
Prevention

2

Description
The second intervention group: All patients have been taken to the operating room then after premedication with 0.1 milligram per kilogram of midazolam, intravenous cannula number 20 have been inserted in non-dominant dorsal veins and 10 cc per kilogram of Ringer's lactate serum will be infused . Then the arm will be held higher than body for one minute to drain the blood. The cuff of the sphygmomanometer will be closed on the same arm and inflates up to 20 mmHg above systolic blood pressure. Then 1 milligram per kilogram of lidocaine 1% will be injected intravenously and the cuff will be emptied after one minute. Finally 2 milligram per kilogram of Propofol is then injected over 15 seconds. During the intervention we will record the patient's vital signs, Heart Rate, Blood Pressure, and movements and speech rate one minute before injection of Propofol and in the first minute after injection in a questionnaire.
Category
Prevention

3

Description
The control group: All patients have been taken to the operating room then after premedication with 0.1 milligram per kilogram of midazolam, intravenous cannula number 20 have been inserted in non-dominant dorsal veins and 10 cc per kilogram of Ringer's lactate serum will be infused . Then the arm will be held higher than body for one minute to drain the blood. The cuff of the sphygmomanometer will be closed on the same arm and inflates up to 20 mmHg above systolic blood pressure. Then 2 cc of normal saline will be injected intravenously and the cuff will be emptied after one minute. Finally 2 milligram per kilogram of Propofol is then injected over 15 seconds. During the intervention we will record the patient's vital signs, Heart Rate, Blood Pressure, and movements and speech rate one minute before injection of Propofol and in the first minute after injection in a questionnaire.ed in a questionnaire.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Children's Hospital
Full name of responsible person
Sedigheh Shahhoseini
Street address
Isfahan Imam Hossein Hospital., Esteghlal Sq., Imam Khomeini st
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
No

Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Ahmad Karimi hasan abadi
Position
Intern student
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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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