# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jul 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**

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Iran (Islamic Republic of)

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**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
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## Sponsors / Funding sources

**1**

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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
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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