Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of preventive effect of injection paracetamol and lidocaine in reducing pain caused by intravenous injection of propofol in children aged 4 to 6 years

Protocol summary

Study aim
Comparison of preventive effect of injection paracetamol and lidocaine in reducing pain caused by intravenous injection of propofol in children aged 4 to 6 years

Design
A randomized, Triple-blinding clinical trial, with the parallel groups, Phase 3 on 90 patients

Settings and conduct
In this randomized three-blind randomized clinical trial study, 90 children candidate for inguinal surgery under general anesthesia with propofol presented at Imam Hossein Hospital in Isfahan will be included in the study and will be randomly divided into 3 groups. One minute before anesthesia with propofol, patients in the first group will receive paracetamol, in the second group lidocaine and in the third group normal saline. Then the agitation score, pain score and hemodynamic parameters of the patients will be evaluated and compared between the three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include children 4-6 years, having the American Association of Anesthesiologists (ASA) I and II, candidate for surgery under general anesthesia with propofol. Exclusion criteria include having underlying diseases (including liver, cardiovascular, neurological, metabolic disease, dermatitis), and having drug allergies.

Intervention groups
Intervention group 1: Patients in this group are injected with 1 mg / kg intravenous paracetamol one minute before propofol administration. Intervention group 2: Patients in this group are injected with 1% lidocaine 1 mg / kg one minute before propofol administration. Control group: Patients in this group are injected with 2 cc of normal saline one minute before propofol administration.

Main outcome variables
Agitation score; Pain score; Moderate arterial pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N34**
Registration date: **2021-05-30, 1400/03/09**
Registration timing: **prospective**

Last update: **2021-05-30, 1400/03/09**
Update count: **0**

Registration date
2021-05-30, 1400/03/09

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-05, 1400/03/15

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of preventive effect of injection paracetamol and lidocaine in reducing pain caused by intravenous injection of propofol in children aged 4 to 6 years

Public title
Evaluation of preventive effect of injection paracetamol and lidocaine in reducing pain caused by intravenous injection of propofol in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children 4-6 years Has the American Association of Anesthesiologists (ASA) One and Two Candidate for inguinal surgery under general anesthesia with propofol

Exclusion criteria:
Has underlying diseases (including liver, cardiovascular, neurological, metabolic disease, dermatitis) Having drug allergies

Age
From **4 years** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 90 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into three groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the three study groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, paracetamol, lidocaine, and placebo are prepared by the pharmacist and placed in coded packages, and delivered daily to an anesthesiologist, who prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

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

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2021-03-14, 1399/12/24

Ethics committee reference number
IR.MUI.MED.REC.1399.1155

Health conditions studied

1

Description of health condition studied
Inguinal surgery

ICD-10 code
K40

ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Pain score

Timepoint
During injection of propofol

Method of measurement
Behavioral scale derived from the Face, Leg, Activity, Cry, Consolability (FLACC)

2

Description
Agitation score

Timepoint
During injection of propofol

Method of measurement
According to Richmond criteria

3

Description
Mean Arterial Pressure
Timepoint
Before and one minute after the intervention
Method of measurement
Monitoring device

4

Description
Hear rate
Timepoint
Before and one minute after the intervention
Method of measurement
Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in this group are injected with 1 mg / kg intravenous paracetamol one minute before propofol administration.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in this group are injected with 1% lidocaine 1 mg / kg one minute before propofol administration.
Category
Treatment - Drugs

3

Description
Control group: Patients in this group are injected with 2 cc of normal saline one minute before propofol administration.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital in Isfahan
Full name of responsible person
Sedighe Shah-Hosseini
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Imam Khomeini street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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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
Sedigheh Shah-Hosseini
Position
Associate Professor
Latest degree
Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available