Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial in comparison between Propofol and Isofluran in blood glucose change in general anesthesia in child between 4-6 years old

Protocol summary

Summary

In pediatric dentistry general anesthesia was recommend after all behavioral management method are failed. Stress, fear and fasting of child during operation can cause change in blood glucose level and sever blood glucose change can cause apnea, syncope and delay in recovery. This study design by randomized non - blind clinical trial and the aim of this study is determine and compare blood glucose change, before operation and anesthesia induction, after anesthesia induction and trachea intubation, after operation and before hospital discharge with intravenous anesthesia by Propofol and inhalation anesthesia by Isofluran in children between 4-6 years old refer to dentistry hospital branch of Isfahan medical University. Children are select for study when in complete health statement and haven't any surgery operation past year and contraindication for Propofol and Isofluran use. Then parental consent and preoperative fasting instruction is obtained at the same. After refer, children are reassessment for general health and if they haven't any surgery prevention, the cloths are changed and are sent to operation room. Children are select randomly for Propofol and Isofluran anesthesia groups, then if child haven't any problem IV line is done, unless they are sedated with 50% N2O, 50% O2 and 5% Isofluran and when they don't response to vocal irritants IV line done. Anesthesia induction in Isofluran group is achieved with Sodium thiopental 6mg/kg, Fentanyl 1µg/kg and Atracurium 0.8mg/kg, in Propofol group is performed with Propofol 2.5-3.5 mg/kg, Fentanyl 1µg/kg and Atracurium 0.8mg/kg. Anesthesia maintenance in Isofluran group is performed with 50% N2O, 50% O2 and 1.5% Isofluran and in Propofol group is achieved with 50% N2O, 50% O2 and 9mg/kg/hr Propofol. After finger disinfection blood glucose assessment is perform with drop of blood by glucometer (Accu-chek), before operation and anesthesia induction, after anesthesia induction and trachea intubation, after operation and before hospital discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109034224N17**
Registration date: **2012-04-07, 1391/01/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-07, 1391/01/19

Registrant information

Name
Nasser Kaviani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 1792 2858
Email address
kaviani@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad Khorasgan University of medical sciences, Dental College.

Expected recruitment start date

2011-02-04, 1389/11/15

Expected recruitment end date

2011-11-06, 1390/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial in comparison between Propofol and Isofluran in blood glucose change in general anesthesia in child between 4-6 years old

Public title
Comparison blood glucose change in intravenous anesthesia with Propofol and inhalation anesthesia with Isofluran in child between 4-6 years old that candidate for dental procedure in general anesthesia.

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria: children between 4-6 years old; parental consent; complete general health consideration; no history of surgery within a year; no contraindication in Isofluran and Propofol use. Exclusion criteria: medical problem during anesthesia.

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad Khorasgan University, College of dentistry

Street address
College of dentistry, Islamic Azad University khorasgan branch, university Blvd, Arghavaniyeh, eastern jey

City
Khorasgan

Postal code
158-81595

Approval date
2011-03-12, 1389/12/21

Ethics committee reference number
77

Health conditions studied

1

Description of health condition studied
blood glucose change

ICD-10 code
E16.0

ICD-10 code description
Hypoglycemia (spontaneous) - drug- induced

Primary outcomes

1

Description
Blood glucose

Timepoint
pre operative before anesthesia induction, post anesthetic induction and trachea intubation and post operative before hospital discharge

Method of measurement
glucometer (Accu-chek)

Secondary outcomes

empty

Intervention groups

1

Description
Blood glucose measurement during general anesthesia in Propofol group with Propofol 2.5-3.5 mg/kg, Fentanyl 1µg/kg and Atracurium 0.8mg/kg.

Category
Diagnosis

2

Description
Blood glucose measurement during general anesthesia in Isofluran group with Sodium thiopental 6mg/kg, Fentanyl 1µg/kg and Atracurium 0.8mg/kg.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Medical University, Isfahan Dental College.

Full name of responsible person
Dr Naser Kaviani

Street address
Dental academy, University of Medical Sciences,

Darvazeh Shiraz square, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery for Research of Dental College- Islamic Azad University of Khorasgan

Full name of responsible person

Dr Vahid Esfahanian

Street address

Islamic Azad University khorasgan branch, university Blvd, Arghavaniyeh, eastern jey

City

Khorasgan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellery for Research of Dental College- Islamic Azad University of Khorasgan

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan Dental College- Isfahan Medical University

Full name of responsible person

Dr Naser Kaviani

Position

Doctor of Anesthesia

Other areas of specialty/work

Street address

Dental academy, University of Medical Sciences, Darvazeh Shiraz square, Isfahan

City

Isfahan

Postal code

73461-8174

Phone

+98 31 1792 2858

Fax

Email

Kaviani@dnt.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

College of dentistry, Islamic Azad University of Khorasgan branch

Full name of responsible person

Hajar Mohebi niya

Position

Student of dentistry

Other areas of specialty/work

Street address

College of dentistry, Islamic Azad University khorasgan branch, university Blvd, Arghavaniyeh, eastern jey

City

Isfahan

Postal code

81595-158

Phone

Fax

Email

moheby14@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty