Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of remifentanil on recovery conditions among healthy children candidate for dentistry under general anesthesia

Protocol summary

Study aim
Examine the effects of remifentanil on recovery conditions among healthy children candidate for dental practices under general anesthesia
Design
A randomized, controlled, double-blind, placebo-controlled clinical trial
Settings and conduct
This study is a parallel double blind randomized clinical trial that will be performed on healthy children aged 3-6 years old referred to pediatric ward of Dental School of Isfahan University of Medical Sciences.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study, 3-6 years old children, referred for dental practices under general anesthesia, lack of any special diseases, lack of allergy to anesthesia drugs, lack of previous experience of general anesthesia Non-inclusion criteria: Chronic diseases such as hepatic or kidney diseases, cardiovascular diseases, hemorrhagic diseases, overweight and obese children, children with cerebral palsy and use of sedative drugs that interfere with agitation
Intervention groups
Anesthesia induction in both intervention and control groups will be performed equally using 5 mg/kg sodium thiopental, 1 µg/kg fentanyl, and 0.6 µg/kg atracurium. To anesthesia maintenance, intervention group will receive remifentanil with propofol and control group will receive propofol.
Main outcome variables
Recovery condition

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170624034726N2**
Registration date: **2020-02-10, 1398/11/21**
Registration timing: **prospective**

Last update: **2020-02-10, 1398/11/21**
Update count: **0**
Registration date
2020-02-10, 1398/11/21

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-19, 1399/01/31
Expected recruitment end date
2020-10-21, 1399/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of remifentanil on recovery conditions among healthy children candidate for dentistry under general anesthesia

Public title
Effects of remifentanil on recovery conditions among healthy children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study 3-6 years old children Referred for dental practices under general anesthesia Lack of any special disease Lack of allergy to anesthesia drugs Lack of any previous experience of anesthesia
Exclusion criteria:
Chronic diseases such as hepatic or kidney diseases cardiovascular diseases hemorrhagic diseases overweight and obese children children with cerebral palsy use of sedative drugs that interfere with agitation
Age
From **3 years** old to **6 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals who are eligible for inclusion will be divided into two groups using simple random method. Individuals will be randomly assigned to remifentanil or propofol by an expert. All the study subjects and the original researcher will be unaware of the existing grouping until the end of the study, and the assignment will be performed by another person who has no knowledge of the research process. The anesthetist will inject the medications.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be a double blind study. Drugs injection will be done by anesthesiologist and assessor of recovery conditions and participants will not aware of type of drug used for anesthesia maintenance.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2019-07-12, 1398/04/21
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.466

Health conditions studied

1

Description of health condition studied
Recovery condition
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Patient discharge time
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Blood pressure
ICD-10 code
R03.0
ICD-10 code description
Elevated blood-pressure reading, without diagnosis of hypertension

Primary outcomes

1

Description
Recovery conditions
Timepoint
After leaving operating room
Method of measurement
Questionnaire

Secondary outcomes

1

Description

Patient discharge time
Timepoint
After leaving operating room
Method of measurement
Questionnaire

2

Description
Blood pressure
Timepoint
After leaving operating room
Method of measurement
Digital sphygmomanometer

Intervention groups

1

Description
Intervention group: Anesthesia induction in both intervention and control groups will be performed using 5 mg/kg sodium thiopental, 1 µg/kg fentanyl and 0.6 µg/kg atracurium. Then, the patient will be connected to an anesthesia machine with a respiratory rate of 10 cc/kg and a respiratory rate of 15 cc. The volume and number of breaths will be controlled using a capnograph. The intervention group will received remifentanil 0.4 µg/kg and then 1 µg/kg for initial loading, 100 µg/kg propofol and 50% N2O and 50% oxygen.
Category
Treatment - Drugs

2

Description
Control group: To anesthesia maintenance, the control group will receive 100 µg/kg propofol and then 1 µg/kg for initial loading, 50% N2O and 50% oxygen.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric ward, School of Dentistry, Isfahan University of Medical Sciences
Full name of responsible person
Reza Salari-Moghaddam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Nosrat Nourbakhsh
Position
Assistant professor
Latest degree
Specialist
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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