

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Name

Nosrat Nourbakhsh

Name of organization / entity

School of dentistry, Esfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 remifentanyl 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 remifentanyl 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

Isfahan

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 receive remifentanyl 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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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?
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