Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of sevoflurane with Remifentanil plus Propofol on recovery conditions in adolescent patient with movement disorders candidate for dental treatment under general anesthesia.

Protocol summary

Study aim

Determining comparative study of recovery conditions in adolescent patient with movement disorders under general anesthesia with two pharmacological diets of sevoflurane with remifentanil plus propofol

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 30 patients. The random number table is used for randomization.

Settings and conduct

The person evaluating the recovery conditions and the participants are unaware of the type of drug injected. For this purpose, the injector and the person evaluating the recovery conditions are different. This study is done in the operating room of the Faculty of Dentistry of Isfahan University of Medical Sciences. Adult patients with movement disorders to perform dental work under general anesthesia, after clinical evaluation by an anesthesiologist and filling out a general information questionnaire and consent form, enter the study. Using a Random number table, they fall into the category of intervention or control. Ricovery conditions are then assessed with the "Nursing Delirium Screening Scale" checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The desire to participate in the study, Patients over 18 years of age, Patients with movement disorders, Patients are candidates for dental treatment under general anesthesia Exclusion criteria: People who are allergic to eggs or soy, Known allergies, Chronic diseases including heart disease, bleeding disorders, liver disease and kidney disease

Intervention groups

Intervention group: To maintain anesthesia, sevoflurane drug with MAC: 1.85 is used. Control group: To maintain anesthesia, Rimifentanil is taken with Propofol (Propofol: 3 mg / kg body weight, followed by Remifentanil: 1 µg / kg body weight per minute).

Main outcome variables

Recovery period; The amount of delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100621004224N38**
Registration date: **2020-05-13, 1399/02/24**
Registration timing: **prospective**

Last update: **2020-05-13, 1399/02/24**
Update count: **0**

Registration date

2020-05-13, 1399/02/24

Registrant information

Name

Nasser Kaviani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

kaviani@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-26, 1399/03/06

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of sevoflurane with Remifentanil plus Propofol on recovery conditions in adolescent patient with movement disorders candidate for dental treatment under general anesthesia.

Public title
Effects of sevoflurane with Remifentanil plus Propofol on recovery conditions
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The desire to participate in the study Patients over 18 years of age Patients with movement disorders Patients are candidates for dental treatment under general anesthesia
Exclusion criteria:
People who are allergic to eggs or soy Known allergies Chronic diseases including heart disease, bleeding disorders, liver disease and kidney disease
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind and the injecting person and the person evaluating the recovery conditions are different. For this purpose, an out-of-study person is used to assess recovery conditions.The person evaluating the recovery conditions is not aware of the medication used for anesthesia. Participants are also unaware of the type of drug injected
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfehan University of Medical Sciences
Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave., Isfehan Town,
City
Isfehsn
Province
Isfehan
Postal code
8174673461
Approval date
2020-02-23, 1398/12/04
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.756

Health conditions studied

1

Description of health condition studied
Movement disorders
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Recovery score on "Nursing Delirium Screening Scale" Checklist
Timepoint
5,10 and 15 minuts after entering recovery
Method of measurement
"Nursing Delirium Screening Scale" Checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: to maintain anesthesia, sevoflurane USP inhaled drug from Piramal Company is used. The drug is given to the patient at a dose of MAC: 1.85 through a tracheal tube with a vaporizer for the drug sevoflurane.
Category
Other

2

Description
Control group: To maintain anesthesia, Rimifentanil is taken with Propofol (Propofol: 3 mg / kg body weight, followed by Remifentanil: 1 µg / kg body weight per minute). Depending on whether the patient is shaking or shows signs of alertness in response to the situation, further injection of the drug (remifentanil: 0.5 µg per kg body weight or propofol 0.5-1 mg / kg body weight) is done. The drugs are injected within 10-15 seconds.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
The operating room of the Faculty of Dentistry, Isfehan University of Medical Sciences

Full name of responsible person
Naser Kaviani

Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave., Isfehan Town,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

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
Naser Kaviani

Position
Consultant

Latest degree
Ph.D.

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Consultant

Latest degree
Ph.D.

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

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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