

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Determination of Bispectral index scores of patients under dental treatment in children between 4-7 years old assigned for general anesthesia under Propofol and Isofloran regimes.

Protocol summary

Summary

The aim of this study is supportive care service by assessment the correlation of Bispectral index scores of patients under dental treatment in children assigned for general anesthesia under Propofol and Isofloran regimes. Inclusion Criteria: Systemic Condition: ASA I, ASA II; Uncooperative children dentistry operation candidate for general anaesthesia; children between 4-7 years old; Exclusion Criteria: Exist of Hypoxia; Arrhythmia; Pain in recovery room; Agitation; Nausea; The time of general anesthesia less than 60 or more than 90 minutes; Using sedate or sedation drug by the children interfering. In this study 32 healthy children between 4-7 years that they candidate for treatment of dentistry are divided in to two groups at random. In both BIS device will use. Bispectral index (BIS) is one of several technologies which purport to monitor depth of anesthesia. The BIS monitor provides a single dimensionless number, which ranges from 0 (equivalent to EEG silence) to 100 (equivalent to fully awake and alert). A BIS score between 40 and 60 indicates an appropriate level for general anesthesia, as recommended by the manufacturer. In group 1 general anesthesia will maintain by intravenous Propofol and in group 2 by inhalation of Isofloran 1%. BIS score is recorded for each child every 10 minute since general anesthesia onsets. After gathering samples data will be analyzed with pair-test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013032212848N1**
Registration date: **2013-06-25, 1392/04/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-25, 1392/04/04

Registrant information

Name

Dana Tahririan

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of Bispectral index scores of patients under dental treatment in children between 4-7 years old assigned for general anesthesia under Propofol and Isofloran regimes.

Public title

Brain activity during general anesthesia and recovery conditions under tow general anesthesia regimes.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion Criteria: Systemic Condition: ASAI, ASAll; Uncooperative children dentistry operation candidate for general anaesthesia; children between 4-7 years old; Exclusion Criteria: Exist of Hypoxia; Arrhythmia; Pain in recovery room; Agitation; Nausea;The time of general anesthesia less than 60 or more than 90 minutes; Using sedate or sedation drug by the children interfering.

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Dental College, Isfahan University of Medical Sciences

Street address

Isfahan Dental College, Isfahan University of Medical Sciences, HezarJarib Street, Isfahan

City

Isfahan

Postal code

Approval date

2012-05-26, 1391/03/06

Ethics committee reference number

391468

Health conditions studied

1

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

F93.8

ICD-10 code description

Other childhood emotional disorder

2

Description of health condition studied

recovery conditions

ICD-10 code

f10,f11,f1

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes

1

Description

Consciousness and brain activity which can be read through the BIS device connected to the patient.

Timepoint

Every ten minute as general anesthesia begins, by a By technician unaware of the topic of the study.

Method of measurement

By recording from the BIS device

Secondary outcomes

1

Description

Agitation in recovery room.

Timepoint

Every ten minute in recovery room by an unaware(topic of strudy and used regime) technician

Method of measurement

Sikich- lerman index

Intervention groups

1

Description

intervention:intravenous propofol100 µg/Kg/min for maintainance dose.

Category

Prevention

2

Description

intervention:isoflorane1% for maintainance dose.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Dental College, Isfahan University of Medical Sciences

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Aminallah Tavangar

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences, Shohadaye Soffe Street

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

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

Name of organization / entity

Isfahan Dental College, Isfahan University of Medical Sciences

Full name of responsible person

Dr.Dana Tahririan

Position

Specializes Asistant

Other areas of specialty/work

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Position

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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