

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

BIS (Bispectral Index Score) after sedation with Midazolam and Propofol combined with Remifentanil vs. Ketamine in pediatric dentistry:A randomized clinical trial study

Protocol summary

Summary

Objectives: a lot of children with caries need immediate and serious dental treatment don't accept the treatment due to fear of local anesthesia. For optimum result gaining in pediatric dentistry, using sedation seems to be a fair solution. Design: In this clinical study we compared two drug combinations, propofol/midazolam/remifentanil combination versus propofol/midazolam/ketamine to see which one effects better according to Bispectral index scaling system. Setting and conduct: Childs dental treatment will be done by two different combinations of medicine through sedation. Participants including major eligibility criteria: 32 agitated and incorporative children between the 3 to 7 years old were collected randomly for the study. Inclusion Criteria: Healthy Systemic Condition; Uncooperative children dentistry operation candidate for sedation; children between 3-7 years old; Exclusion Criteria: The time of sedation more than 45 minutes. Intervention: a Bispectral Index Score sensor is connected to each child and do the sedation with two different combination of medicines. main outcome measures variables: Consciousness and brain activity are measured by the Bispectral index score device connected to the patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042512848N2**
Registration date: **2015-09-09, 1394/06/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-09, 1394/06/18

Registrant information

Name

Dana Tahririan

Name of organization / entity

Dental college, Isfahan University of Medical Sciences, Isfahan

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

BIS (Bispectral Index Score) after sedation with Midazolam and Propofol combined with Remifentanil vs. Ketamine in pediatric dentistry:A randomized clinical trial study

Public title

Brain activity during sedation under tow anesthesia

regimes

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion Criteria: Healthy Systemic Condition; Uncooperative children dentistry operation candidate for sedation; children between 3-7 years old; Exclusion Criteria: The time of sedation more than 45 minutes; accidental problem during the work.

Age

From **3 years** old to **7 years** old

Gender

Both

Phase

2-3

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

Ethics committee Of 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

2014-03-08, 1392/12/17

Ethics committee reference number

393398

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

Primary outcomes

1

Description

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

Timepoint

Every five minute as sedation 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

success in sedation

Timepoint

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

Method of measurement

DSTG(Dental Sedation Teachers Group)index

Intervention groups

1

Description

0.1µg/kg remifentanil

Category

Diagnosis

2

Description

0.5 mg/kg ketamine

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Medical Science

Full name of responsible person

Street address

Pediatric Part, Isfahan Dental College, Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan

City

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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 Sose 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

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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