

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### evaluation and Comparison the effectiveness of oral melatonin versus midazolam as premedication in children undergoing general anesthesia for dental treatment with contral group

#### Protocol summary

##### Summary

Objectives: evaluation and comparison the effectiveness of oral melatonin and midazolam as premedication on sedation and post operative complications of candidate children for dental treatment under general anesthesia with contral group Design:in this double blinded study oral melatonin and midazolam as premedications for children who are candidate of dental treatment under general anesthesia are used. these medications are compared in these aspects: 1.reduction of vein access anxiety.2.manifestation of medical complications after anesthesia( hypoxia ,nausea)3.post tretment agitation4. patient's need of anesthetics 5.recovery period duration6.child seperation anxiety7.children sedation before coming to operative room Setting and conduct: 132 children with 3-6 years old who need dental treatment under general anesthesia, after assigning informed consent are included in this study.children are divided into 3 equal groups randomly and these medications are used in each group:group1: 40 minutes before anesthesia induction,5ml of 0.5 mg/kg oral midazolam. group2:40 minutes before anesthesia induction,5ml of 0.5 mg/kg oral melatonin.(maximum dosage of 20mg) group3:40 minutes before anesthesia induction,5ml of dextrose and water in this double blinded study oral melatonin and midazolam as premedication for children who are candidate of dental treatment under general anesthesia are used. these medications are compared in these aspects: 1.reduction of vein access anxiety.2.manifestation of medical complications after anesthesia( hypoxia ,nausea)3.post treatment agitation4. patient's need of anesthetics 5.recovery period duration6.child separation anxiety7.children sedation before coming to operative room Participants:132 children with 3-6 years old who need dental treatment under general anesthesia, after assigning informed consent are included in this study.

Inclusion criteria include:1.Children should be ASA1 or ASA2 (Systemic disease is confinder)2.Children cooperation should be in grade 1 or 2 of Frankl classification 3.children should not use benzodiazepin, barbitorate or analgesics.(usage of these drugs can interfere with true effect od melatonin and midazolam)4.children should not have bodily or mentally disabilities.5.children should not have contraindication for anesthesia with propofol.6.children should not have history of convulsion exclusion criteria include:1.If complications was found during operation 2.if oeration takes less than 30 minutes or more than 120 minutes .3.if parents are not cooperative and consent is not assigned main outcome measures: vein access anxiety;manifestation of medical complications after anesthesia( hypoxia ,nausea);post treatment agitation4. patient's need of anesthetics ;recovery period duration;child separation anxiety;children sedation before coming to operative room

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201602074224N36**

Registration date: **2016-05-11, 1395/02/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-11, 1395/02/22

##### Registrant information

##### Name

Nasser Kaviani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

**Phone**

+98 31 1792 2858

**Email address**

kaviani@dnt.mui.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research- Dental school- Esfahan university of Medical Sciences

**Expected recruitment start date**

2016-03-19, 1394/12/29

**Expected recruitment end date**

2016-08-21, 1395/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

evaluation and Comparison the effectiveness of oral melatonin versus midazolam as premedication in children undergoing general anesthesia for dental treatment with contral group

**Public title**

evaluation and comparison the effectiveness of oral melatonin and midazolam as premedication on sedation and post operative complications of candidate children for dental treatment under general anesthesia with contral group

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria include:Children should be ASA1 or ASA2 (Systemic disease is confinder); Children cooperation should be in grade 1 or 2 of Frankl classification ; children should not use benzodiazepin, barbitorate or analgesics.(usage of these drugs can interfere with true effect od melatonin and midazolam); children should not have bodily or mentally disabilities; children should not have contraindication for anesthesia with propofol.6.children should not have history of convulsion exclusion criteria include:If complications was found during operation ; If oeration takes less than 30 minutes or more than 120 minutes ; If parents are not cooperative and consent is not assigned

**Age**

From **3 years** old to **6 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **132**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committe of Esfahan university of medical sciences

**Street address**

ethics committe, dentistry school, Esfahan university of medical sciences, Hezarjarib St., Esfahan

**City**

Esfahan

**Postal code****Approval date**

2015-07-04, 1394/04/13

**Ethics committee reference number**

IR.MUI.REC.1394.394511

**Health conditions studied****1****Description of health condition studied**

anxiety

**ICD-10 code**

y49

**ICD-10 code description**

Psychotropic drugs, not elsewhere classified

**Primary outcomes****1****Description**

agitation

**Timepoint**

20 minutes

**Method of measurement**

agitation scale

**Secondary outcomes****1****Description**

nausea

**Timepoint**

24 hours

**Method of measurement**

nausea scale

**Intervention groups****1****Description**

group1: 40 minutes before anesthesia induction, 5ml of 0.5 mg/kg oral midazolam.

**Category**

Treatment - Drugs

**2****Description**

group3: 40 minutes before anesthesia induction, 5ml of dextrose and water

**Category**

Treatment - Drugs

**3****Description**

group2: 40 minutes before anesthesia induction, 5ml of 0.5 mg/kg oral melatonin. (maximum dosage of 20mg)

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

operative room of dental school, Torabinejad research center, Esfahan university of medical sciences

**Full name of responsible person**

Dr. Reyhaneh Faghihian

**Street address**

operative room of dental school, Torabinejad research center, Esfahan university of medical sciences

**City**

Esfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research- Esfahan university of medical sciences

**Full name of responsible person**

Kobra Hosseinpour

**Street address**

Vice chancellor for research, Dental school, Esfahan university of medical sciences, Hezarjarib St., Esfahan, Iran

**City**

Esfahan

**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- Esfahan 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**

Esfahan university of medical sciences

**Full name of responsible person**

Dr Reyhaneh Faghihian

**Position**

Resident of pediatric dentistry

**Other areas of specialty/work****Street address**

Pediatric Department, Esfahan university of medical sciences, Esfahan

**City**

Esfahan

**Postal code****Phone**

+98 31 3651 6128

**Fax****Email**

reyhane.fgh@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

postgraduate student of pediatric dentistry Esfahan university of medical sciences

**Full name of responsible person**

Dr Reyhaneh Faghihian

**Position**

doctor of medicine

**Other areas of specialty/work****Street address**

number23, nour st., Sepahan Shahr, Esfahan

**City**

Esfahan

**Postal code****Phone**

+98 31 3651 6128

**Fax**

**Email**

reyhane.fgh@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan university of medical sciences

**Full name of responsible person**

Dr Reyhaneh Fgahihian

**Position**

Resident of pediatric dentistry

**Other areas of specialty/work**

**Street address**

Department of Pediatric dentistry, Dental school,  
Esfahan university of medical sciences, Esfahan

**City**

Esfahan

**Postal code**

**Phone**

+98 31 3651 6128

**Fax**

**Email**

reyhane.fgh@gmail.com

**Web page address**

## 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*