

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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	Randomization description Blinding (investigator's opinion) Double blinded
Email address kaviani@dnt.mui.ac.ir	Blinding description Placebo Used
Recruitment status Recruitment complete	Assignment Parallel
Funding source Vice chancellor for research- Dental school- Esfahan university of Medical Sciences	Other design features
Expected recruitment start date 2016-03-19, 1394/12/29	Secondary Ids empty
Expected recruitment end date 2016-08-21, 1395/05/31	Ethics committees
Actual recruitment start date empty	1
Actual recruitment end date empty	Ethics committee
Trial completion date empty	Name of ethics committee Ethics committe of Esfahan university of medical sciences
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	Street address ethics committe, dentistry school, Esfahan university of medical sciences, Hezarjarib St., Esfahan
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	City Esfahan
Purpose Treatment	Postal code
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	Approval date 2015-07-04, 1394/04/13
Age From 3 years old to 6 years old	Ethics committee reference number IR.MUI.REC.1394.394511
Gender Both	Health conditions studied
Phase 2	1
Groups that have been masked No information	Description of health condition studied anxiety
Sample size Target sample size: 132	ICD-10 code y49
Randomization (investigator's opinion) Randomized	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

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City

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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**

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Full name of responsible person

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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