

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

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Name of organization / entity

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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

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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

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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

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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