Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 consont 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 consont 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 Pediatrc 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