Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Efficacy of premedication with melatonin versus oral midazolam in pediartic patients

Protocol summary

Summary

Objectives: This study aimed to compare the efficacy of premedication with melatonin and oral midazolam in pediatric dental patients. Design: This non-randomized double blind clinical trial was conducted on 23 uncooperative 2-6 years old with completely negative Frankel behavioral rating scale. Cases in ASA I were included who had no signs of any cold or flu. Children in group I received 0.5mg/kg melatonin orally one hour before the IV induction while group II received 0.5mg/kg oral midazolam 30 minutes prior to the IV induction procedures in their first session. Each child acted as self control receiving the other premedication drug. Sedation was scored using Houpt sedation rating scale. Physiological parameters of blood pressure, heart rate and SPO2 were recorded at start of treatment and in 15 minute intervals in addition to potential side effects including dizziness, nausea, vomiting and sleepiness at 1 and 6 hours of the treatment end. Parental satisfaction rate was recorded beside that of the clinician. This Study is at phase II.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101616106N2**
Registration date: **2016-12-27, 1395/10/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name

Ghassem Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

zarghi@sbmu.ac.ir

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of premedication with melatonin versus oral midazolam in pediartic patients

Public title

Efficacy of premedication with melatonin versus oral midazolam in pediartic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Uncooperative chidren aged 2-6 years, completely negative Frankel behavioral scale approved by two pediatric dentists, ASA I for systemic health with at least two teeth requiring treatments like pulpotomy, restoration, stainless steel crown or extraction for two separate dental visits. Exclusion criteria: Any systemic disease with contraindications for sedation or premedication, cold symptoms, nasal obstruction,

respiratory infection, limited neck movement, macroglossia, tonsillar hypertrophy, micrognathia, mouth opening limitation, not being able to remain NPO and having less than two teeth requiring the same treatment.

Age
From **2 years** old to **6 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **23**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double 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 in Biomedical Research, Research Institute of Dental Sciences Shahid Beheshti Unive

Street address
Office of Ethics, Research Institute for Dental Sciences, 5th floor,Dental school, Shahid Beheshti University of Medical Sciences, Student blvd, Evin

City
Tehran

Postal code
1983663113

Approval date
2016-06-21, 1395/04/01

Ethics committee reference number
ir.sbmu.rids.rec.1395.209

Health conditions studied

1

Description of health condition studied
dental anxiety and management

ICD-10 code
V

ICD-10 code description
Mental and behavioural disorders

Primary outcomes

1

Description
sedation

Timepoint
At the IV Administration step

Method of measurement
Houpt scale

Secondary outcomes

1

Description
evaluation of recovery process and medication side effects

Timepoint
After the treatment ends and IV sedation reversed

Method of measurement
Observation and asking parents

Intervention groups

1

Description
"Intervention group: Oral Melatonin tablet of 3 mg was grounded and added to 1cc of sweetened drinking water before being administered an hour prior to the actual IV sedation episode."

Category
Treatment - Drugs

2

Description
"Control group: Oral Midazolam Vial of 5mg was added to 1cc sweetened drinking water before being administered half an hour prior to the actual IV sedation episode."

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ghassem Ansari

Street address
Department of Pediatric Dentistry

City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Office of Vice Dean of Research, Floor 5, Shahid Beheshti University of Medical Sciences, Student Blvd, Evin
City
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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

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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