Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A Clinical Trial to Compare Oral Midazolam and Oral Promethazine Effect as Premedication on Sedation among Uncooperative Children undergoing dental procedures

Protocol summary

Summary

Aim: Comparing oral midazolam and oral promethazine premedication on child's cooperation before ketamin/Midazolam IV administration in pediatric dentistry. Material and Method: This unicenter cross-over randomized double blind clinical trial is carried out on 6 children aged 2-6 years referred to the fellowship unit of dental school due to their fear and multiple dental needs. Patients' selection is based on the following main inclusion criteria: being ASA I or II classification and scored 1 in Frankl Behavior scale and exclusion criteria: no systemic contraindications for sedation; nasal obstruction; respiratory infection; mouth opening limitation; macroglossia; tonsillar hypertrophy. Each patient is scheduled for two subsequent visits to receive one of the two premedications before IV sedation. Each patient will be considered as his/her control (self-control) and patients will randomly be assigns to either intervention group 1 (oral Midazolam as premed in 1st visit and oral Promethazine in 2nd visit) and intervention group 2 (oral Promethazine as the premed in 1st visit and oral Midazolam in 2nd visit) through random number table. Being 6 hours NPO is instructed before sedation. IV Ketamin/Midazolam will be administered half an hour after premedication and following dental treatment will be done. Vital signs will be controlled every 15 minutes as a base before drug administration. Patient's cooperation for IV sedation is measured using HOUPT scale. Drugs side effects including nausea and vomiting , dizziness and sleepiness will be recorded at the end of sedation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120516106N3**

Registration date: **2017-10-29, 1396/08/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-29, 1396/08/07

Registrant information

Name

Ghassem Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

drgansari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Dental Research Center, Research Institute of Dental Sciences, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial to Compare Oral Midazolam and Oral Promethazine Effect as Premedication on Sedation

among Uncooperative Children undergoing dental procedures

Public title
Oral Midazolam Vs Oral Promethazine Premedication Effect on Dental Sedation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: uncooperative children aged 2-6 years; completely negative Frankle behavioral scale; ASA I or II for systemic health; two teeth requiring the same treatment in two separate sessions Exclusion Criteria: any systemic disease with contraindication for sedation or premedication ;nasal obstruction;respiratory infection; mouth opening limitation; macroglossia; tonsillar hypertrophy
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: **26**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Crossover
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 Univ
Street address
Ethics committee Office, 5th floor, Research Institute for Dental Sciences, Dental school, Shahid Beheshti University of Medical Sciences, Daneshjoo blvd, Evin
City
Tehran
Postal code
1983663113
Approval date
2014-09-23, 1393/07/01
Ethics committee reference number
IR.SBMU.RIDS.REC.21

Health conditions studied

1

Description of health condition studied
dental anxiety and management
ICD-10 code
F00-F99
ICD-10 code description
Mental and behavioural disorders

Primary outcomes

1

Description
Patient's Cooperation for Sedation
Timepoint
At the IV Administration step
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Nausea and vomitting
Timepoint
After the end of treatment and sedation
Method of measurement
Questionair

2

Description
Sleeepiness
Timepoint
After the end of treatment and sedation
Method of measurement
Questionair

3

Description
Dizziness
Timepoint
After the end of treatment and sedation
Method of measurement
Questionair

Intervention groups

1

Description
Intervention group 1 :In 1st session oral Midazolam suspension premedication (0.5mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV

Midazolam (0.5 mg/kg). Then in 2nd session oral Promethazine (1 mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV Midazolam (0.5 mg/kg) administration.

Category

Treatment - Drugs

2

Description

Intervention group 2 : In 1st session oral Promethazine suspension premedication (0.5mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV Midazolam (0.5 mg/kg). Then in 2nd session oral Midazolam (1 mg/kg) is administered half an hour before IV Ketamin (2mg/kg) and IV Midazolam (0.5 mg/kg) administration.

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, Shahid Beheshti Medical University,Daneshjoo Blvd, Evin, Chamran Highway

City

Tehran

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 Chancellor of Research, 5th Floor, Shahid Beheshti University of Medical Sciences, Daneshjoo blvd, Evin, Chamran Highway

City

Tehran

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Position

Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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