

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 HOUP 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

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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

IR.SBMU.RIDS.REC.21

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

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 vomiting

Timepoint

After the end of treatment and sedation

Method of measurement

Questionair

2

Description

Sleepiness

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

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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 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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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