Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of oral and buccal midazolam for pediatric dental sedation: A randomized, cross-over, clinical trial for efficacy, acceptance and safety

Protocol summary

Summary

Providing a safe and efficient dental treatment for a young patient is a challenge for the dentist and the child. The purpose of this study was to investigate the effectiveness, safety and acceptability of buccal Midazolam in dental pediatric patients and to compare it with oral Midazolam. Methods: Eighteen uncooperative healthy children aged 2.5-6 years were randomized to each of buccal midazolam (0.3mg/kg) or oral midazolam (0.5mg/kg) at the first visit, the alternative has been used at the second visit in a cross-over manner. The study took place at pediatric dentistry clinic of Shahed University, Tehran, Iran from November 2011 to June 2012. The patients` vital signs and behavioral scores were recorded. The patient, the operator and the observer were blinded to the applied medication. Post operatively, patients` and parents` satisfaction were assessed by Visual Analogue Score and a questionnaire respectively. The P-Value was set at 0.05 for significance level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020312350N1**
Registration date: **2013-05-11, 1392/02/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-11, 1392/02/21

Registrant information

Name

Rahil Ahmadi

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 9210

Email address

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral and buccal midazolam for pediatric dental sedation: A randomized, cross-over, clinical trial for efficacy, acceptance and safety

Public title

Comparison of oral and buccal midazolam for pediatric dental sedation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: those who needed bilateral and identical restorative and pulp treatment requiring 2 or more dental visits and were unable to tolerate the dental procedure with behavior management techniques. Those with contraindication to Midazolam, upper respiratory tract infection, tonsilar hypertrophy were excluded.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

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

Shahed University Ethics Committee

Street address

Shahed University, Oppiste Imam Khomeini Holey shrine.

City

Tehran

Postal code

Approval date

2011-03-12, 1389/12/21

Ethics committee reference number

41/166599

Health conditions studied

1

Description of health condition studied

Stress in healthy uncooperative dental patient

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress

Timepoint

At discharge

Method of measurement

VAS

2

Description

Parents acceptebility

Timepoint

At discharge

Method of measurement

Questionnaire

3

Description

Physiologic outcomes

Timepoint

Before treatment,each 10 minutes, at discharge

Method of measurement

Pulse oximeter

Secondary outcomes

1

Description

Parental acceptability

Timepoint

Discharge time

Method of measurement

Questionnair

Intervention groups

1

Description

Group 1 received 0.5 mg/kg oral Midazolam syrup (Amsed, 2.5 mg/ml, Dales Pharmaceutical, England) 30 -45 minutes before treatment

Category

Treatment - Drugs

2

Description

Group 2 was given 0.3 mg/kg buccal Midazolam (Epistatus, 10mg/ml, Special Product Ltd, England), 15-30 minutes prior dental procedure. The other regimen was used at the second appointment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahed University

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dental school- Shahed University
Full name of responsible person
Dr Abbasi
Street address
No. 73, Italia st.
City
Tehran
Grant name
پژوهانه
Grant code / Reference number
717
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dental school- Shahed University
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
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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