

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of efficacy and safety of "Midazolam Syrup" versus" PO Midazolam " in dental treatment of uncooperative 4-6 years old patients.

Protocol summary

Summary

Dental fear and behavior management problems are the main barriers of noncompliance with dentistry. The prevalence is about 5-20% and 14% respectively. In such patients who can not cooperate with dentist, sedation by the means of Pharmacological domain is an alternative. Among sedative drugs in pediatric dentistry, Midazolam due to its safety and appropriate efficacy has gained considerable attention. The purpose of present study is : 1/ to compare the safety and efficacy of Midazolam syrup with PO Midazolam (as an Iranian drug formulation with lower drug price) and 2/ To determine Dental fear, General anxiety and different aspects of child's personality as well as the relationship between above mentioned factors and sedative response. Method and material: 82 uncooperative children (Frankl 1,2) aged 4 to 6 years will randomly receive one of drug prescriptions blindly. Children with hypertrophic tonsils /adenoids (Brotsky>2), more than 24kg, History of allergy to Benzodiazepines, Sleep apnea will be excluded. The behavior will be appraised according to North Carolina Behavior rating score. Dental fear, General anxiety and different aspects of child's personality will be assessed by means of CFSS-DS, SDQ and Conner's parental rating scale, which are completed by mothers. Dental treatment will be initiated 30 minutes after drug administration. Physiological parameters will be evaluated before and during the course of treatment every 15 minutes. These parameters include SPO2, Heart rate, Respiratory rate and Blood pressure. Child's behavior will be evaluated by means of North Carolina Behavior rating score during injection, cavity preparation and restoration by one practitioner.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302031861N4**

Registration date: **2013-02-08, 1391/11/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-08, 1391/11/20

Registrant information

Name

Katayoun Salem

Name of organization / entity

Tehran Azad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 0966

Email address

nastaranegar@gmail.com

Recruitment status

Recruitment complete

Funding source

Deputy of Research, Guilan University of Medical Sciences and Main Researcher's personal expense.

Expected recruitment start date

2013-01-02, 1391/10/13

Expected recruitment end date

2013-05-03, 1392/02/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of "Midazolam Syrup" versus" PO Midazolam " in dental treatment of uncooperative 4-6 years old patients.

Public title

Evaluation of Midazolam Efficacy and Safety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Uncooperative behavior (Frankl 1,2); age 4 to 6 years; ASA I Exclusion criteria: Hypertrophic tonsils /adenoids (Brodsky>2); weight >24 kg; History of allergy to Benzodiazepines; Sleep apnea; history of common cold/ Respiratory disease during the past two weeks.

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

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

Guilan University of Medical Sciences, Deputy of Research and Technology

Street address

Gaz Square, West Shahid Beheshti blvd, Opposite Sepah Bank

City

Rasht

Postal code

41938-93345

Approval date

2013-01-01, 1391/10/12

Ethics committee reference number

3910354611

Health conditions studied

1

Description of health condition studied

Anxiety, Uncooperation in Pediatric Dental Treatment

ICD-10 code

F93.1

ICD-10 code description

Phobic anxiety disorder of childhood

Primary outcomes

1

Description

Sedation

Timepoint

Sedation: At the time of injection, cavity preparation and restoration

Method of measurement

By the means of North Carolina Behavior Rating Scale

2

Description

Physiological parameters(Systolic and diastolic Blood pressure), Heart rate, Respiratory rate, SPO2

Timepoint

Before drug administration, at the onset of treatment, and then every 15 minutes

Method of measurement

Blood pressure:Digital blood pressure cuff,Heart rate: pulse oximeter, Respiratory rate: counting the breathing movements of thorax, SPO2: Pulseoximeter

Secondary outcomes

1

Description

Dental fear, General Anxiety, Child's personality (different aspects)

Timepoint

Before treatment

Method of measurement

Questionnaires: CFSS-DS, SDQ, Conner's parental rating scale

Intervention groups

1

Description

Intervention: PO midazolam 2.5 mg/ml Control: mdazolam surup Amsed 2.5 mg/ml

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan Dental Polyclinic

Full name of responsible person

Sara Ataee, Dental nurse,

Street address

Imam blvd, Opposite Pardis Hotel, Polyclinic of Dental School

City

Rasht

Phone

+98 13 1326 3605

Fax**Email**

k_salem@gums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan Dental School

Full name of responsible person

Katayoun salem

Position

Assistant Professor

Other areas of specialty/work**Street address**

Rasht, Iakan Site, Dental School

City

Rasht

Postal code**Phone**

+98 13 1326 3605

Fax**Email**

k_salem@gums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Guilan University of Medical Sciences, Deputy of Research and Technology

Full name of responsible person

Ms Komaiee

Street address

Gaz Sq. West Shahid Beheshti blvd, Opposite Sepah Bank, Deputy of Research

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan University of Medical Sciences, Deputy of Research and Technology

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**

Guilan Dental School

Full name of responsible person

Katayoun Salem

Position

Assistant professor, member of Dental Research center

Other areas of specialty/work**Street address**

Rasht, Lakan Site, Lakan road, After Police station, Guilan University Complex, Dental School

City

Rasht

Postal code**Person responsible for updating data****Contact****Name of organization / entity**

Guilan Dental school

Full name of responsible person

Katayoun Salem

Position

ssitant professor, Member of research center

Other areas of specialty/work**Street address**

Rasht, Lakan site, Dental School

City

Rasht

Postal code**Phone**

+98 13 1326 3605

Fax**Email**

k_salem@gums.ac.ir

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