Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of sedative effect of syrup of midazolam and injectable midazolam (as oral) on behavior of 3-6 years old uncooperative children in dentistry

Protocol summary

Summary

The aim of this study is comparison of sedative effect of the syrup midazolam and injectable midazolam as oral on 3-6 years old uncooperative children under dental treatment.This double blind cross over clinical trial is done on 20 children 3-6 years old referred to dental school. The samples according to inclusion criteria: healthy children as ASA1 classification; uncooperative negative and definitely negative as Frankle scale and exclusion criteria: cold; allergy and tonsil hypertrophy are divided into two groups randomly. After obtaining informed written consent, orally and written instructions before conscious sedation, at first meeting the one group receive combination of 0.5 mg/kg syrup midazolam +1 mg/kg hydroxyzine (regimen A) and the other group receive combination of 0.5 mg/kg injectable midazolam with fruit juice as oral+ 1 mg/kg hydroxyzine (regimen B). In the second session, the first group receive regimen B and the second group B receives regimen A. Dental treatment starts by a pedodontist who is blind to type of regimen 20-30 minutes after drug administration and lidocaine 2% with adrenaline 1/100000 anesthesia. Sedation level and the child's behavior based on Houpt scale evaluates by a member of teamwork who does not aware of the type of regimen. Arterial blood oxygen saturation (SpO2) and heart rate (HR) by finger pulse oxymeter before administration, starting, every 15 minutes during the work, after work and discharge patients records in related form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406171882N5**
Registration date: **2016-02-25, 1394/12/06**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-02-25, 1394/12/06

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Facualty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2014-01-05, 1392/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedative effect of syrup of midazolam and injectable midazolam (as oral) on behavior of 3-6 years old uncooperative children in dentistry

Public title

Effectiveness of oral and injectable midazolam on children behavior in dentistry

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Healthy 3-6 years old children as ASA1 classification؛ Uncooperative negative and definitely negative according to Frankle scale؛ Having at least two sessions of dental treatment Exclusion criteria: Cold and allergy؛ Tonsils hypertrophy more than 50%; Severe obesity

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features
Randomization is carried with the toss of a coin.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee, Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti Dental School, Daneshjo Blvd, Evin

City
Tehran

Postal code

Approval date
2013-09-04, 1392/06/13

Ethics committee reference number
19

Health conditions studied

1

Description of health condition studied
Fear and anxiety

ICD-10 code
F00-F01-F0

ICD-10 code description
Organic, including symptomatic, mental disorders

Primary outcomes

1

Description
Conscious sedation

Timepoint
Every 15 minutes

Method of measurement
Houpt scale

Secondary outcomes

1

Description
SpO2

Timepoint
Every 15 minutes

Method of measurement
pulse oximeter

2

Description
Heart Rate

Timepoint
Every 15 minutes

Method of measurement
pulse oximeter

Intervention groups

1

Description
0.5 mg/kg Syrup of Midazolam(Amsed, England) +1 mg/kg Hydroyzine(Abureyhan, Iran). Waiting time for sedation 20 to 30 minute. Treatment time: 30 minute

Category
Treatment - Drugs

2

Description
0.5 mg/kg injectable Midazolam as oral (Darupakhsh, Iran) + 1 mg/kg Hydroxyzine(Abureyhan, Iran). Waiting time: 20-30 minutes. Treatment time:30 minutes

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Dental School

Full name of responsible person
Dr. Masoud Fallahinejad Ghajari

Street address
Shahi Beheshti Dental School, Daneshjo Blvd, Evin

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Masoud Fallahinejad Ghajari

Street address
Shahid Beheshti Dental School, Daneshjo Blvd, Evin

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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 for 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
Dental Research Center, Shahid Beheshti Dental School

Full name of responsible person
Dr. Sarira Zomorodian

Position
Dental student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
Associate Professor, Department of Pediatric Dentistry

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Position
Associate Professor, Department of Pediatric Dentistry

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