Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparison of the sedative effectiveness of oral combinations of midazolam/ketamine and midazolam /hydroxyzine in uncooperative pediatric dental patients

Protocol summary

Summary

PURPOSE: This study was undertaken to compare the effectiveness of oral combinations of midazolam/ketamine and midazolam /hydroxyzine for sedation in pediatric dental patients. METHODS: this study was a clinical trial of 25 uncooperative children, aged 37 to 56 months in need of at least 2 restorative visits. The subjects were assigned randomly to receive either the combination of midazolam 0.5 mg/kg and ketamine 5mg/kg or midazolam 0.5 mg/kg and hydroxyzine 2 mg/kg prior to the beginning of dental treatment at the first appointment. The alternative drug regimen was administered at the second appointment two weeks later. All subjects also received 50% nitrous oxide/oxygen during the treatment. The child's behavior: (1) sleeping; (2) crying; (3) body movement and (4) overall behaviors, was evaluated during injection and procedure by an independent clinician who was unaware of the drug given to the child.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804092102N1**
Registration date: **2010-01-16, 1388/10/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-01-16, 1388/10/26

Registrant information

Name

Shahnaz Maghsoudi

Name of organization / entity

Hamadan university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences

Expected recruitment start date

2007-10-23, 1386/08/01

Expected recruitment end date

2007-12-24, 1386/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the sedative effectiveness of oral combinations of midazolam/ketamine and midazolam /hydroxyzine in uncooperative pediatric dental patients

Public title

sedation in dentistry

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: uncooperative children, ages 37 to 56 months, in need of at least 2 restorative visits, parents acceptance. Exclusion criteria: vomiting before or during treatment.

Age

From **3 years** old to **5 years** old

Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **25**
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
Shiraz university of medical sciences
Street address
Research affairs department - main building of Shiraz university of medical sciences - Zand street
City
Shiraz
Postal code
71345-1978
Approval date
2008-03-16, 1386/12/26
Ethics committee reference number
86-3904-CT

Health conditions studied

1

Description of health condition studied
Dentistry-related anxiety
ICD-10 code
F40
ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
Conscious sedation
Timepoint
30 min in midazolam/ketamine group and 45 min in midazolam /hydroxyzine group
Method of measurement
observation-Houpt index

Secondary outcomes

empty

Intervention groups

1

Description
either the combination of midazolam 0.5 mg/kg and ketamine 5mg/kg or midazolam 0.5 mg/kg and hydroxyzine 2 mg/kg prior to the beginning of dental treatment
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz dentistry faculty
Full name of responsible person
Dr.Tahere Eskandarian
Street address
Pedodontic Department - Dentistry Faculty - Ghomabad Street - Ghasrodasht Street
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz university of medical sciences
Full name of responsible person
Mohammadhossein Dabbaghmanesh
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Research affairs department - main building of Shiraz university of medical sciences-Zand street
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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
Shiraz 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

Hamadan dentistry faculty

Full name of responsible person

Shahnaz Maghsoudi

Position

Assiatant professor-pedodontist

Other areas of specialty/work

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Full name of responsible person

Shahnaz Maghsoudi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

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