

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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)

Phone

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Email address

sh.maghsoudi@umsha.ac.ir

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

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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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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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Contact

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Full name of responsible person

Shahnaz Maghsoudi

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Other areas of specialty/work

Street address

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Postal code

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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