

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of oral administration versus intramuscular Ketamine, Midazolam, Atropine combination on sedation in pediatric dentistry

Protocol summary

Summary

The study aimed to evaluate the safety and effectiveness of pharmaceutical composition Ketamine, Midazolam and Atropine and compare the sedative effect of oral administration of this compound with intramuscular in the referent uncooperative children who need a dental treatment at emergency department. A crossover clinical trial was conducted on 31 uncooperative children aged 1-4, who required dentistry with local anesthesia and were definitely negative based on the Frankel scale. Cases (First group) were randomly given ketamine (10 mg/kg) and midazolam (0.2 mg/kg) and atropine (0.02 mg/kg) orally in a visit. While they (The second group) were given Ketamine (6 mg/kg), Midazolam (0.05 mg/kg) and Atropine (0.02 mg/kg) through the intramuscular route in second visit. Both the researchers and patients are unaware of the research process. A computer programming is used to randomly select patients of two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030926983N1**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-28, 1395/03/08

Registrant information

Name

Nilgoon Pasdar

Name of organization / entity

Babol University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral administration versus intramuscular Ketamine, Midazolam, Atropine combination on sedation in pediatric dentistry

Public title

Comparison of oral administration versus intramuscular Ketamine, Midazolam, Atropine combination on sedation in pediatric dentistry

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Uncooperative children were confirmed by two pediatric dentists ranked as definitely negative the Frankel scale who referred for dental treatment under local anesthesia, requiring at least two dental visits for two similar dental treatments. Exclusion criteria: Having systemic disease, medical contradictions

Age

From **1 year** old to **4 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of
Medical Sciences

Street address

Arabi. St. Yaman. St. Chamran Highway, Tehran

City

Tehran

Postal code

Approval date

2011-07-06, 1390/04/15

Ethics committee reference number

9017

Health conditions studied

1

Description of health condition studied

Dental

ICD-10 code

K02.8

ICD-10 code description

Other dental caries

Primary outcomes

1

Description

Ocular response

Timepoint

Every one hour

Method of measurement

Eyes closed or nystagmus present, eyes open or no
nystagmus

2

Description

Response to voice

Timepoint

Every one hour

Method of measurement

None-incoherent

3

Description

Response to touch

Timepoint

Every one hour

Method of measurement

Not arousable, sleepy, awake

4

Description

Sedation

Timepoint

Every one hour

Method of measurement

Ocular response, response to voice and touch

Secondary outcomes

empty

Intervention groups

1

Description

Children in control group receive cocktail of 10 mg/kg
Ketamine, 0.2 mg/kg Midazolam and 0.02 mg/kg
Atropine orally.

Category

Treatment - Drugs

2

Description

In intervention group, each child receive an injection
cocktail of 6 mg/kg Ketamine, 0.05 mg/kg Midazolam and
0.02 mg/kg Atropine through the gluteal region at their
first dental session.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Pediatric Hospital

Full name of responsible person

Dr Ghasem Ansari

Street address

Shariati Ave, District 3, Tehran

City

Tehran

2**Recruitment center****Name of recruitment center**

The Department of Pediatric Dentistry of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Ghasem Ansari

Street address

Shariati Ave, District 3, Tehran

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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 Ghasem Ansari

Street address

Arabi. St. Yaman. St. Chamran Highway, Tehran

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Tehran

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**

Babol University of Medical Sciences

Full name of responsible person

Neda Amani

Position

Surgical Tecnologist

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Dentist

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Web page address**Person responsible for updating data****Contact****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*