

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the efficacy of intrabuccal ketamine and oral midazolam for sedation in children with oral procedures

Protocol summary

Study aim

Our purpose of this study is to compare the efficacy, safety and side effects of oral midazolam and intrabuccal ketamine in the sedation of children who required oral procedures, in order to provide a safe and appropriate way of doing this.

Design

Randomized, parallel group, single-blind, clinical trial

Settings and conduct

In this study, children with oral procedure referring to the emergency department are divided into two groups using randomized blocking method. oral midazolam at a dose of 0.5 mg/ kg or intrabuccal ketamine at a dose of 3 mg/ kg is used for children sedation. Ramsay sedation scale was used for assessment of sedation level. A score of four is considered as adequately sedated. If it does not reach this level after 20 minutes, one half of the dose of the initial drug is repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children between 6 months and 12 years of age require oral procedures, which parents have the consent to participate in this study. Exclusion criteria: known contraindications to the use of study drugs and having lung and neuromuscular disease.

Intervention groups

The intervention group received a single dose of ketamine intrabuccal (3 mg/kg) and the control group receives a single dose of oral midazolam (5 mg/kg).

Main outcome variables

The main outcome of the study is the efficacy and safety of Intrabuccal Ketamine for sedation in patients requiring the oral procedure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038549N7**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Farhad Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 8804

Email address

drfarhadheydari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-31, 1397/05/09

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of intrabuccal ketamine and oral midazolam for sedation in children with oral procedures

Public title

Efficacy of intrabuccal ketamine for sedation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Required oral procedures Take informed consent

Exclusion criteria:

Sensitivity to benzodiazepines Low blood pressure
Having a lung disease Having Nervous-Muscular
Disorders Known contraindications to study drug

Age

From **6 months** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization with Table of random numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

The drugs are prepared and packaged by a pharmacist who is not aware of the study and are divided into two groups A and B.A package containing ketamine and the other containing Midazolam. Individuals randomly receive one package. Except for a nurse who prescribes the drug, no other person, such as a doctor, researchers, parents of children, data collectors, outcome assessors, and data analysts are all kept blinded to the allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Alzahra hospital, Sofe Ave., Shahid Keshvari Blvd.

City

Isfahan

Province

Isfahan

Postal code

8177777645

Approval date

2018-09-02, 1397/06/11

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.197

Health conditions studied

1

Description of health condition studied

Oral procedure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation level of the patient

Timepoint

Every 5 minutes after drug administered

Method of measurement

Physical exam

Secondary outcomes

1

Description

Side effects

Timepoint

Every 5 minutes after drug administered

Method of measurement

Physical exam

2

Description

Blood oxygen saturation level

Timepoint

Every 5 minutes after drug administered

Method of measurement

Physical exam

3

Description

The time interval from taking the drugs to the adequate sedation

Timepoint

Every 5 minutes after drug administered

Method of measurement

Record time

4

Description

The time interval from taking the drug to the child's full

consciousness

Timepoint

Every 5 minutes after drug administered

Method of measurement

Record time

5

Description

The parents' satisfaction

Timepoint

After the child's consciousness

Method of measurement

Question from parents

6

Description

Pulse rate per minute

Timepoint

Every 5 minutes after drug administered

Method of measurement

Physical exam

7

Description

Respiratory rate per minute

Timepoint

Every 5 minutes after drug administered

Method of measurement

Physical exam

Intervention groups

1

Description

Intervention group: Intrabuccal ketamine 3 mg/kg

Category

Treatment - Drugs

2

Description

Control group: Oral midazolam 0.5 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Saeed Majidinejad

Street address

Kashani Hospital, kashani Street

City

Isfahan

Province

Isfahan

Postal code

817777645

Phone

+98 31 3233 0091

Email

smajidinejad@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjooy javanmard

Street address

Isfahan University of Medical Sciences, P.O. Box 319,
Hezar-Jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

817777645

Phone

+98 31 3792 3071

Email

drfarhadheydari@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

No 7, Aria Building, Sohrevardi Ave.

City

Isfahan

Province

Isfahan

Postal code

817777645

Phone

+98 31 3776 9818

Fax

Email

drfarhadheydari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable