

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the efficacy of oral midazolam and intranasal midazolam in sedation for diagnostic procedures (radiology and sonography, CT scan) in children referred to the ED

Protocol summary

Study aim

Comparison of the efficacy of oral midazolam and midazolam in the nasal passages for relaxation in diagnostic radiology (CT scan, radiology and ultrasound) of children referred to the emergency department of Bahonar

Design

The first participant in the study is randomly assigned to one of the groups based on randomization table (Appendix 2 below), and the next patient will be assigned so. 15 min before the procedure, children in intranasal midazolam group (0.2 mg / kg) and 30 minutes before the procedure, patients in oral midazolam group (0.5 mg / kg) receive the drug , then If the target sedation was done , the child will be transferred to a diagnostic radiologic procedure (CT scan, radiology, and ultrasound). After completing the diagnostic action, the data sheet is completed and the patient's vital signs are again checked. If the child was in good condition he or she undergo other diagnostic or therapeutic process. if unstable, the child will be resuscitated. finally the care sheet will be delivered to parents.

Settings and conduct

clinical trial at Bahonar hospital ED

Participants/Inclusion and exclusion criteria

A study was conducted on 74 children aged 2 to 12 years old for diagnostic radiology (CT scan, radiology, and ultrasonography) to the emergency department at Bahonar Hospital in 1964-09.

Intervention groups

The first participant in the study is randomly assigned to one of the groups (intranasal and oral groups) based on randomization table (Appendix 2 below), and the next patient will be assigned so. And no one knows anything about allocation.

Main outcome variables

sedation

General information

Reason for update

Acronym

The comparison of effectiveness of oral midazolam and intranasal midazolam on sedation of children

IRCT registration information

IRCT registration number: **IRCT20171009036661N3**

Registration date: **2018-12-03, 1397/09/12**

Registration timing: **retrospective**

Last update: **2018-12-03, 1397/09/12**

Update count: **0**

Registration date

2018-12-03, 1397/09/12

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3335 6220

Email address

m.mayel@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2015-05-22, 1394/03/01

Actual recruitment end date

2018-02-09, 1396/11/20

Trial completion date

2018-03-16, 1396/12/25

Scientific title

Comparison of the efficacy of oral midazolam and intranasal midazolam in sedation for diagnostic procedures (radiology and sonography, CT scan) in children referred to the ED

Public title

The effect of intranasal midazolam on children sedation

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

age 2 to 12 years old mild to moderate traumatic brain injury no concomitant nasal trauma or nasal anatomic abnormality

Exclusion criteria:

1. Parental dissatisfaction GCS $\leq$ 8 Unstable hemodynamic

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **74**

Actual sample size reached: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

The first participant in the study is randomly assigned to one of the groups based on randomization table (Appendix 2 below), and the next patient will be assigned so. 15 min before the procedure, children in intranasal midazolam group (0.2 mg / kg) and 30 minutes before the procedure, patients in oral midazolam group (0.5 mg / kg) receive the drug , then If the target sedation was done , the child will be transferred to a diagnostic radiologic procedure (CT scan, radiology, and ultrasound). After completing the diagnostic action, the data sheet is completed and the patient's vital signs are again checked. If the child was in good condition he or she undergo other diagnostic or therapeutic process. if unstable, the child will be resuscitated. finally the care sheet will be delivered to parents.

Blinding (investigator's opinion)

Single blinded

Blinding description

The first participant in the study is randomly assigned to one of the groups based on randomization table (Appendix 2 below), and the next patient will be assigned so. And no one knows anything about allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Kerman University of Medical Sciences

Street address

Somayeh Cross road - Research Center - Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7613747181

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

ir.kmu.rec.1395.361

Health conditions studied

1

Description of health condition studied

Pediatrics Sedation

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

Sedation Level

Timepoint

15 minutes after intranasal method and 30 minutes after oral method

Method of measurement

Nialc Wilton Method

Secondary outcomes

1

Description

Parent's level of satisfaction from procedure

Timepoint

After completing procedure

Method of measurement

Questionnaire

Intervention groups

1

Description

The first participant in the study is randomly assigned to one of the groups based on randomization table (Appendix 2 below), and the next patient will be assigned so. And no one knows anything about allocation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital in Kerman

Full name of responsible person

Dr. Massoud mayel

Street address

National Garden Square. Qarani Street Shahid Bahonar Hospital .

City

kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

masoud.mayel@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

dr. pardakhti

Street address

Tahmasebabad Four Way Deputy of research and technology

City

kerman

Province

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Postal code

7613747181

Phone

+98 34 3223 5011

Email

masoud.mayel@gmail.com

Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Massoud mayel

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Emergency Medicine Department - Shahid Bahonar Hospital - Kerman - IRAN

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7613747181

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Massoud mayel

Position

Assistant Professor استادیار

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Bahonar Educational hospital
Full name of responsible person
Dr. Massoud Mayel
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
میدان باغملی، خیابان قرنی
City
kerman
Province
Kerman
Postal code

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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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