Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 midasolam 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≤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 midasolam 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
Questionnare

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
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7613747181
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+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
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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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Person responsible for scientific inquiries

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Person responsible for updating data

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Dr. Massoud Mayel
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Assistant Professor
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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
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