Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Evaluation of the Optimal Dosage for the Efficacy of Submucosal Midazolam Administration to Induce Sedation in Children Undergoing Diagnostic Procedures

Protocol summary

Study aim
Evaluation of the Optimal Dosage for the Efficacy of Submucosal Midazolam Administration to Induce Sedation in Children Undergoing Diagnostic Procedures

Design
A clinical trial without a parallel control group, double-blind, randomized

Settings and conduct
The study population was all children undergoing the diagnostic procedure (CT scan) that referred to the emergency department of Kashani and Al-Zahra education training hospitals in Isfahan during 2017-2018. The researcher administered Midazolam with an insulin syringe into the patient's oral mucosa along the molar teeth (4-6 teeth). Then, the onset time of the sedation in the child was recorded. The RAMSAY sedation scale (0-5) was used to measure the sedation level of the child. Moreover, as the child is supposed to be immobilized in the diagnostic procedures, reaching the sedation level of three and four was considered desirable so that the child would have no movement during the therapeutic-diagnostic procedures. In addition, the duration of drug action (from the onset of sedation to the child's return to complete consciousness) was calculated and recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The age range of over three months up to five years; Children requiring diagnostic procedures such as CT scan; Exclusion criteria: The patients with excessive sensitivity to Benzodiazepines; Medical disorder of shock or blood pressure; Alcohol intoxication; Poor vital signs; Pulmonary diseases; Myasthenia gravis or musculoskeletal disorders

Intervention groups
The children were divided into three groups of 33 each. The first group received 0.3 mg / kg midazolam, the second group received 0.4 mg midazolam and the third group received 0.5 mg midazolam.

Main outcome variables
The length of the sedative effect

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N20**
Registration date: **2019-10-05, 1398/07/13**
Registration timing: **prospective**

Last update: **2019-10-05, 1398/07/13**
Update count: **0**

Registration date
2019-10-05, 1398/07/13

Registrant information

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Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-24, 1398/08/02

Expected recruitment end date
2020-04-21, 1399/02/02

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Optimal Dosage for the Efficacy of Submucosal Midazolam Administration to Induce Sedation in Children Undergoing Diagnostic Procedures

Public title
Subcutaneous administration of midazolam in pediatric diagnostic procedures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age range of over three months up to five years Children requiring diagnostic procedures such as CT scan
Exclusion criteria:
The patients with excessive sensitivity to Benzodiazepines Medical disorder of shock or blood pressure Alcohol intoxication Poor vital signs Pulmonary diseases Myasthenia gravis or musculoskeletal disorders
Age
From **3 months** old to **5 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients randomly selected one of the packets, as a result of which they were divided into three groups, each consisting of 33 patients. Three packets with A, B, and C labels that represented one of the 0.3, 0.4, and 0.5 mg/kg selective doses of Midazolam.
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher and the participant have been blinded in this trial. The doses of midazolam are prepared daily by the emergency nurse without the knowledge of the researcher and are available to the researcher. And the participant does not know what drug he is taking.
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
Isfahn University of Medical Sciences, Hezar jarib st, Isfahan
City
Isfahan
Province
Isfehan
Postal code
7346181746
Approval date
2018-01-17, 1396/10/27
Ethics committee reference number
IR.MUI.MED.REC.1396.3.829

Health conditions studied

1

Description of health condition studied
sedation during procedure
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The length of the sedative effect
Timepoint
From the beginning of sedation to the return of the child to full consciousness
Method of measurement
Computing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention group received midazolam at a dose of 0.3 mg / kg
Category
Treatment - Drugs

2

Description
Intervention group: The second intervention group received midazolam at a dose of 0.4 mg / kg

Category
Treatment - Drugs

3

Description
Intervention group: The third intervention group received midazolam at a dose of 0.5 mg / kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital
Full name of responsible person
Saeed Majidinejad
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2

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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Ziba Farajzadegan
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farajzadegan@med.mui.ac.ir
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
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
Esfahan University of Medical Sciences
Full name of responsible person
Saeed Majidinejad
Position
Assistant Professor of Emergency Medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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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
No - There is not 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information about the main outcome can be shared.

When the data will become available and for how long
Start the access period 4 months after publishing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Use data to complete clinical trial studies

From where data/document is obtainable
Al-Zahra Hospital and Kashani Hospital

What processes are involved for a request to access data/document
After the investigation of researcher request and presentation of required documents will be accessible.

Comments