

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

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

Isfahan

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

Street address

Sofe Blvd, Isfahan Province, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 7539

Email

saeedmajidinejad@yahoo.com

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

Kashani hospital

Full name of responsible person

Saeed Majidinejad

Street address

Kashani Street, Isfahan Province, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 7539

Email

saeedmajidinejad@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Isfahan University of Medical Sciences, Hezar jarib Avne

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3668 0048

Email

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

Street address

Department of Emergency Medicine, School of Medicine, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 7539

Email

saeedmajidinejad@yahoo.com

Person responsible for scientific 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

Street address

Department of Emergency Medicine, School of Medicine, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 7539

Email

saeedmajidinejad@yahoo.com

Person responsible for updating data

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

Street address

Department of Emergency Medicine, School of Medicine, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 7539

Email

saeedmajidinejad@yahoo.com

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