

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison of the effect of Diphenhydramine and oral midazolam sedation on children admitted to Emergency department of Kerman's Bahonar Hospital

#### Protocol summary

##### Study aim

Determination of the effect of oral diphenhydramine and midazolam on sedation (sedation) of children referred to emergency department of Bahonar hospital in Kerman

##### Design

Clinical trial with control group, with parallel groups, without blindness, randomized with sample size 74, of both genders

##### Settings and conduct

This clinical trial study was performed on 74 children aged 1 to 7 years old in Bahonar Kerman hospital for diagnostic procedures. The method of this study was to determine that the first patient referring to the randomly randomized (randomized) The groups were assigned and the next patients were selected.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Children aged 1 to 7 years with mild moderate levels of consciousness Exclusion criteria:1- Parental dissatisfaction 2- GCS  $\leq$ 8 3-Unstable hemodynamics

##### Intervention groups

To the first group, midazolam was administered at a dose of 0.5 mg / kg The second group received diphenhydramine at a dose of 0.5 mg / kg

##### Main outcome variables

Relaxation rate of children referred to the hospital for diagnostic use with oral diphenhydramine and midazolam.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190613043882N1**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **retrospective**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

##### Registration date

2019-07-08, 1398/04/17

##### Registrant information

###### Name

neda naeimi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3226 4071

###### Email address

s.ghasemirad@kmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-01-20, 1397/10/30

##### Expected recruitment end date

2019-04-20, 1398/01/31

##### Actual recruitment start date

2019-01-20, 1397/10/30

##### Actual recruitment end date

2019-04-20, 1398/01/31

##### Trial completion date

2019-04-20, 1398/01/31

##### Scientific title

Comparison of the effect of Diphenhydramine and oral midazolam sedation on children admitted to Emergency department of Kerman's Bahonar Hospital

##### Public title

Comparison of the effect of oral diphenhydramine and midazolam on the sedation of children

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Child 1 to 7 years old With a mild to moderate level of consciousness

**Exclusion criteria:**  
Parental dissatisfaction GCS $\leq$ 83 Absence of hemodynamic stable

**Age**  
From **1 year** old to **7 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **74**  
Actual sample size reached: **74**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients are available by sampling method and were selected using a simple accident method with a random number table.74 blocks including 37 patients in the diphenhydramine group and 37 patients in the midazolam group.30 minutes before starting diagnostic procedure (CT, radiology and sonography), children were given oral metidazolam and oral diphenhydramine.Individual randomization unit and there is no layered randomization.There was no cloak. Analysis was performed using statistical software.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

##### Street address

Ebn-e-Sina St.,Jahad Blvd.,Kerman,Iran

##### City

kerman

##### Province

Kerman

##### Postal code

7619813159

#### Approval date

2019-03-10, 1397/12/19

#### Ethics committee reference number

IR.KMU.REC.1397.520

## Health conditions studied

### 1

#### Description of health condition studied

The effect of sedation of diphenhydramine and midazolam on children

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Average relaxation of diphenhydramine

#### Timepoint

30 minutes before starting radiologic diagnostic procedure

#### Method of measurement

Recovery Scoring Systems

### 2

#### Description

Average relaxation of midazolam

#### Timepoint

30 minutes before starting radiologic diagnostic procedure

#### Method of measurement

Recovery Scoring Systems

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, 30 minutes before the start of the diagnostic radiology protocol (CT, radiology and sonography), children were given oral midazolam from the Caspian Pharmaceutical Company at a dose of 0.5 mg / kg.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: In this group, 30 minutes before the initiation of diagnostic radiology (CT, radiology and sonography), diphenhydramine children were prescribed from the Emad darman Pars Pharmaceuticals Company at a dose of 0.5 mg / kg.

#### Category

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Emergency department of Bahonar hospital in Kerman

**Full name of responsible person**

Sareh GHasemirad

**Street address**

Ebn-e-Sina St.,Jahad Blv.,Kerman.,Iran

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s.ghasemirad@kmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Sareh Ghasemirad

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kerman University of Medical Sciences

**Proportion provided by this source**

1

**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**

Neda Neimi

**Position**

Clinical Assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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