

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 (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

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Sponsors / Funding sources

1

Sponsor

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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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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