Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the sedative effect of intranasal midazolam and dexmedetomidine with for sedation of children1 to 6 year-old undergoing Computerized tomography(CT) scan that referred to emergency department of Kashani and Al-zahra hospitals in Isfahan in 2017

Protocol summary

Study aim

Determination and comparison of the sedation efficacy of intranasal injection of midazolam and dexmedetomidine for CT scan imaging in 1-6 years old children referred to emergency department of Kashani and Alzahra hospitals, Isfahan 2017

Design

The present study is a double-blind clinical trial that 162 patients will be randomly divided into two groups (n1=n2=81). The medication will be prepared by a nurse and placed inside the envelope and labeled A and B. Therefore, both patient and therapist are unaware about the type of treatment.

Settings and conduct

This study was conducted on children referring to Kashani and Al-zahra hospitals in Isfahan for CT scan in 2017. In the first group, Midazolam ,and in the second group, it was administered Dexmedetomidine intranasally. the two medications were used by Mucosal Atomization Device, MAD 300 .A double blind study involving patient and physician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Children's age range , 1 to 6- yearold, requiring diagnostic imaging(CT scan). 2-Parental satisfaction to participate in this study. Exclusion criteria: 1-Excessive sensitivity to medications fo benzodiazepines family and the alfa-agonist drugs 2-Hemodynamic unstability 3-severe hypotension and shock 4-pulmonary disease

Intervention groups

Our study aimed to compare the sedation effect of intranasal injection of Dexmedetomidine and Midazolam in 1-6 years old children who required for CT scan imaging. Intervention group: Will receive Dexmedetomidine by intranasal injection. Control group: Will receive Midazolam by intranasal injection.

Main outcome variables

The beginning of sedation;imaging time(procedure time);blood pressure;pulse rate;blood o2 saturation,recovery time ;side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190509043538N1**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **retrospective**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Ali Bigdeli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 25 3292 2172

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

2018-01-10, 1396/10/20

Actual recruitment end date

2019-01-21, 1397/11/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

Comparison the sedative effect of intranasal midazolam and dexmedetomidine with for sedation of children1 to 6 year-old undergoing Computerized tomography(CT) scan that referred to emergency department of Kashani and Al-zahra hospitals in Isfahan in 2017

Public title

Comparison of the sedative effect of intranasal midazolam and dexmedetomidine for pediatric

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Children's age range from 1 year to 6 years old requires a CT scan. Parental satisfaction to participate in this study.

Exclusion criteria:

Having excessive sensitivity to benzodiazepines and family members as well as alpha agonists Alertness level based on the Glasgow Coma Score less than 15 Having very low blood pressure or shock Having weak and unstable vital signs Having lung disease

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **162**

Actual sample size reached: **143**

Randomization (investigator's opinion)

Randomized

Randomization description

The studied samples will be randomly divided into two groups of 81 individuals by selecting envelopes. Each envelope was contained with one of the two labels A or B representing Midazolam or Dexmedetomidine. Children will be in one of two groups .

Blinding (investigator's opinion)

Double blinded

Blinding description

To meet the double blindness of the study, Midazolam (dose of 0.3 mg /kg) and Dexmedetomidine (dose of 3 mcg /kg) will be prepared daily by the emergency nurse (uninformed) and labeled A or B and also will be available for the researcher daily. The researcher will be prescribed the mentioned medicine by syringe intranasally.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Science

Street address

No.15,Yas building, Sadoughi Ave,Yasaman St,

City

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Province

Isfehan

Postal code

3716937314

Approval date

2017-04-21, 1396/02/01

Ethics committee reference number

Ir.mui.rec.1396.2.076

Health conditions studied

1

Description of health condition studied

Head trauma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Success in sedation intranasally

Timepoint

0,10,20,30 min

Method of measurement

By Ramsay scoring

Secondary outcomes

1

Description

Measurement of blood pressure ; pulse rate; blood oxygen saturation;

Timepoint

0;10;20;30 minutes

Method of measurement

PulseOxymetery;Sphygmomanometer

Intervention groups

1

Description
Intervention group: The intervention group will have received Dexmedetomidine (manufactured by Hospira Co. USA) interanasally. The agent will be prepared daily by a nurse and will prescribed by Intranasal Mucosal Atomization Device (IMAD), that called MAD Nasal 300 (manufactured by Teleflex Medical Co, USA) by dose 3 µg/kg. Up to 1 ml of the medication will be injected in each nostril of nose by a 2 cc syringe (G 22, manufactured by Avapezeshk Co, Iran). The injection of medication is carried out when the patient is being supine position and in resting. Two minutes after injection of medication into the nostrils, the patient can place in sitting position.

Category
Treatment - Drugs

2

Description
Control group: The control group will have received Midazolam (manufactured by Exir Co, Iran) interanasally. The agent will be prepared daily by a nurse and will prescribed by Intranasal Mucosal Atomization Device (IMAD), that called MAD Nasal 300 (manufactured by Teleflex Medical Co, USA) by dose 0.3 µg/kg. Up to 1 ml of the medication will be injected in each nostril of nose by a 2 cc syringe (G 22, manufactured by Avapezeshk Co, Iran). The injection of medication is carried out when the patient is being supine position and in resting. Two minutes after injection of medication into the nostrils, the patient can place in sitting position.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani hospital,Al-Zahra hospital

Full name of responsible person
Ali Bigdeli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Azizkhani ,Reza

Street address
Sufeh Blvd, Al Zahra Hospital, Department of Emergency Medicine

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8174675731

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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
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
Azizkhani ,Reza

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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
No - There is not 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
Not applicable