

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of low dose Dexmedetomidine in reducing the dose of analgesic and sedative medications in the pediatric intensive care unit

Protocol summary

Study aim

Evaluation of efficacy and safety of low dose dexmedetomidine in reducing the dose of analgesic and sedative medications in the pediatric intensive care unit

Design

A phase three, randomized, parallel-group clinical trial with blinded intervention and outcome assessment. Randomization was centralized and computerized with a concealed randomization sequence carried out at <https://www.sealedenvelope.com/>.

Settings and conduct

Sixty children from one year to 12 years old who are hospitalized in the special care department of the hospital and need mechanical ventilation and sedation are examined. The patients will be divided into two groups, and a drug package with a unique code will be delivered to them. The patient, the caregiver, and the investigator will be blind to the package content.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 1 year to 12 years, Admission to pediatric intensive care unit ,under mechanical ventilation and sedation Exclusion criteria: Children receiving Barbiturates, Persistent bradycardia, Hypotension, Cardiac arrhythmia, Involvement of the central nervous system.

Intervention groups

The control group consists of 30 patients and will be anesthetized with 0.1 milligrams per kilogram of intravenous Midazolam and 1 (or more) microgram per kilogram of Fentanyl and placebo. The intervention group consists of 30 patients and will be anesthetized with 0.1 milligram per kilogram intravenous Midazolam and 1 (or more) microgram per kilogram of Fentanyl along with 0.5 microgram per kilogram per hour Dexmedomidine

Main outcome variables

The reduction of Midazolam and Fentanyl dose.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230520058235N1**

Registration date: **2023-07-23, 1402/05/01**

Registration timing: **prospective**

Last update: **2023-07-23, 1402/05/01**

Update count: **0**

Registration date

2023-07-23, 1402/05/01

Registrant information

Name

Najmeh Forouzan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8892 6571

Email address

negar.iker@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low dose Dexmedetomidine in reducing the dose of analgesic and sedative medications in the pediatric intensive care unit

Public title

Effect of Dexmedetomidine in pediatric anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 1 year to 12 years Admission to pediatric intensive care unit (PICU) Under mechanical ventilation and sedation

Exclusion criteria:

Children receiving Barbiturates Persistent bradycardia (less than 5th percentile of normal for age) Hypotension (less than 5th percentile of normal age) Cardiac arrhythmia Involvement of the central nervous system (brain trauma, encephalitis, meningitis...)

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization has been performed using the block randomization table. The block randomization method is designed to randomize subjects into ten blocks consisting of six and four patients resulting in two equally divided groups. This method is used to ensure a balance in sample size across groups over time. Randomization was centralized and computerized with a concealed randomization sequence carried out at <https://www.sealedenvelope.com/>. In this method, a randomization list with unique codes for each patient is generated. Patients will enroll in the study based on the randomization list into medication or placebo groups with a unique code for follow-up. The allocation person will inform the investigators of the patient codes from the list by phone for randomization and blinding.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo will be in coded same packages; a designated person will provide the codes from block randomization via phone. The same person will group the data at the end of the trial, and the expert will perform statistical analysis and after results, the pocket that is with the placebo provider would be opened, and the data will be decrypted. The data regarding harm and benefits of treatment will be provided to the patient and caregiver.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

Street address

2nd floor, School of Nursing and Midwifery, Valiasr and Niayesh junction

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.066

Health conditions studied**1****Description of health condition studied**

Opioid related disorders in pediatric intensive care unit

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes**1****Description**

Determining and comparing the needed total Fentanyl dose in each group

Timepoint

From enrollment up to seven days

Method of measurement

Dose counting

2**Description**

Determining and comparing the needed total Midazolam dose in each group

Timepoint

From enrollment up to seven days

Method of measurement

Dose counting

Secondary outcomes

1

Description

Determining the need for a second sedative drug in each group

Timepoint

From enrollment up to seven days

Method of measurement

Patient file

2

Description

Determining the need for the third sedative drug in each group

Timepoint

From enrollment up to seven days

Method of measurement

Patient file

3

Description

Determining the need for the muscle relaxant in each group

Timepoint

From enrollment up to seven days

Method of measurement

Patient file

Intervention groups

1

Description

Intervention group: In this group, patients will be anesthetized with 0.1 milligram per kilogram of intravenous Midazolam and 1 (or more) micrograms per kilogram of Fentanyl along with 0.2 micrograms per kilogram per hour of Dexmedomidine.

Category

Treatment - Drugs

2

Description

Control group: In this group, they will be anesthetized with 0.1 milligram of intravenous Midazolam per kilogram and 1 (or more) micrograms of Fentanyl per kilogram.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's Hospital

Full name of responsible person

Bahador Mirrahimi

Street address

Mofid Children's Hospital, Mirdamad Junction, Shariaty Ave.

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mirrahimi@sbmu.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaee

Street address

3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Najmeh Forouzan

Position

Clinical Pharmacy Resident

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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School of Pharmacy, Shahid Beheshti University of Medical Sciences, Niayesh Highway, Valiasr Ave, Tehran, Iran.

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

The main outcome will be available.

When the data will become available and for how long

Six months after publishing data.

To whom data/document is available

The data will be available per request for people working in academic institutions.

Under which criteria data/document could be used

The data will be available for using in systematic review and meta-analysis.

From where data/document is obtainable

The data will be available by contacting email; mirrahimi@sbmu.ac.ir.

What processes are involved for a request to access data/document

The data will be available for using in systematic review and meta-analysis.

Comments