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
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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 Dexmedomidine 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Clinical Pharmacy Resident
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Person responsible for updating data

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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 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 available for using in systematic review and meta-analysis.
Comments