Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of effectiveness of dexmedetomidine plus Midazolam and fentanyl plus Midazolam in placement of central venous catheter in Pediatric Intensive Care Unit (PICU)

Protocol summary

Study aim

Comparing the effectiveness of "dexmedetomidine and midazolam" with "fentanyl and midazolam" in the speed of achieving sufficient sedation, determining the amount of drug needed to achieve sufficient sedation, determining hemodynamic changes in central venous catheter placement in the Pediatric Intensive Carr Unit (PICU)

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients

Settings and conduct

This randomized clinical trial is conducted to compare the effectiveness of dexmedetomidine and midazolam with fentanyl and midazolam in central venous catheter placement in the PICU of BuAli Hospital. People are randomly selected by age block and divided into two intervention and control groups in parallel. Dexmedetomidine and fentanyl drugs are prepared and coded in 10 cc syringes in the same composition by the pharmacist on the days when the patient needs catheterization. The patient and the researchers do not know the type of contents of the syringes.

Participants/Inclusion and exclusion criteria

Children 1 month to 18 years needing central venous catheter placement in the PICU are included

Intervention groups

In the intervention group, 1 µg/kg intravenous dexmedetomidine is prescribed for ten minutes along with 0.1 mg/kg injectable midazolam as a loading dose. Dexmedetomidine infusion continues at a rate of 1 µg/kg/hour. The control group recieves the general protocol of the PICU of BuAli Hospital and for sedation, receives fentanyl at a dose of 1 µg/kg for 10 minutes along with midazolam at a dose of 0.1 mg/kg during the procedure. Fentanyl infusion continues at a rate of 1 µg/kg/h.

Main outcome variables

Primary outcome: reaching Ramsay Sedation Scale (RSS) equal to 3 or more; Secondary outcome: end of catheterization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230701058628N2**
Registration date: **2023-07-27, 1402/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-27, 1402/05/05**
Update count: **0**

Registration date

2023-07-27, 1402/05/05

Registrant information

Name

Mohammad Reza Navaeifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 2334

Email address

m.navaeifar@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of dexmedetomidine plus Midazolam and fentanyl plus Midazolam in placement of central venous catheter in Pediatric Intensive Care Unit (PICU)

Public title

Comparison of effectiveness of dexmedetomidine plus Midazolam and fentanyl plus Midazolam in placement of central venous catheter in PICU

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children needing central venous catheter placement in the pediatric intensive care unit

Exclusion criteria:

Presence of bradycardia or hypotension High blood pressure above the 99th percentile Apnea before the study The presence of cardiac conduction disorder in the electrocardiogram before drug administration Patients with American Society of Anaesthesiologists' physical status classification III or higher Known kidney or heart failure History of heart surgery Shock Receiving other anesthetics, sedatives, injectable painkillers

Age

From **1 month** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

After meeting the inclusion criteria for the study, randomization is done by simple randomization method with age block. Dexmedetomidine and fentanyl drugs are similarly prepared and coded in a 10 mL syringe by a pharmacist and provided to the researcher. The patient and the treatment team will not know the nature of the contents of the syringes, and the desired syringe will be delivered to the treatment team daily based on the initial group determined. Only at the end of the study or in case of a complication that requires therapeutic intervention and knowing the name of the drug, the drug code is decoded by the researcher and the name of the drug is provided to the doctor. Before assigning the individuals in groupa, the assigned group is not clear.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted in a double-blind manner. Dexmedetomidine and fentanyl drugs are similarly prepared and coded in a 10 mL syringe by a pharmacist and kept in the refrigerator until use. The patient, the prescribing nurse and the doctor are not aware of the type of therapeutic combination used. Only at the end of the study or in case of a complication that requires therapeutic intervention and knowing the name of the drug, the drug code is decoded by the researcher and the name of the drug is provided to the doctor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4815838477

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.MAZUMS.REC.1401.504

Health conditions studied

1

Description of health condition studied

Viral infection

ICD-10 code

B34

ICD-10 code description

Viral infection of unspecified site

2

Description of health condition studied

Acute lower respiratory infection

ICD-10 code

J22

ICD-10 code description

Unspecified acute lower respiratory infection

3

Description of health condition studied
Virus infections of central nervous system
ICD-10 code
A81
ICD-10 code description
Atypical virus infections of central nervous system

4

Description of health condition studied
Immunodeficiency
ICD-10 code
D84.9
ICD-10 code description
Immunodeficiency, unspecified

5

Description of health condition studied
Renal failure requiring dialysis or plasmaphresis
ICD-10 code
P96.0
ICD-10 code description
Congenital renal failure

Primary outcomes

1

Description
Ramsay Sedation Score equal to or more than 3
Timepoint
Every 5 minutes until 5 minutes after sedation
Method of measurement
Ramsay scale

2

Description
Mean arterial blood pressure
Timepoint
Every 5 minutes until 5 minutes after sedation
Method of measurement
Blood pressure monitor

3

Description
Blood oxygen saturation
Timepoint
Every 5 minutes until 5 minutes after sedation
Method of measurement
Palsoxymeter

4

Description
Heart rate and respiratory rate
Timepoint
Every 5 minutes until 5 minutes after sedation
Method of measurement
تعداد در دقیقه

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, 1 µg/kg intravenous dexmedetomidine is prescribed for ten minutes along with 0.1 mg/kg injectable midazolam as a loading dose. Dexmedetomidine infusion continues at a rate of 1 µg/kg/hour.
Category
Treatment - Drugs

2

Description
Control group: The control group recieves the general protocol of the Pediatric Intensive Care Unit (PICU) of BuAli Hospital and for sedation, receives fentanyl at a dose of 1 µg/kg for 10 minutes along with midazolam at a dose of 0.1 mg/kg during the procedure. Fentanyl infusion continues at a rate of 1 µg/kg/h.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Buali Hospital
Full name of responsible person
Dr. Mohammad Reza Navaeifar
Street address
Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 911 325 2944
Email
m.navaeifar@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person
Pedram Ebrahimnejad

Street address
Vice chancellor for Research, Moallem square, Sari, Iran

City
Sari

Province
Mazandaran

Postal code
4712855689

Phone
+98 11 3448 4800

Email
pebrahimnejad@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Fahimeh Dianati

Position
Resident of Pediatrics

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran

City
Sari

Province
Mazandaran

Postal code
4815838477

Phone
+98 11 3334 2334

Email
pidrc@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Mohammad Reza Navaeifar

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran

City
Sari

Province
Mazandaran

Postal code
4815838477

Phone
+98 11 3334 2334

Fax

Email
m.navaeifar@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Fahimeh Dianati

Position
Resident of Pediatrics

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran

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Sari

Province
Mazandaran

Postal code
4815838477

Phone
+98 11 3334 2334

Email
pidrc@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Contact Dr.Mohammad Reza Navaeifar. Email: dr.navaifar@gmail.com

When the data will become available and for how long

Informations will send within few days after the email

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Contact Dr.Mohammad Reza Navaeifar. Email: dr.navaifar@gmail.com

From where data/document is obtainable

Email

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

Informations will send within few days after the email.

Comments