Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of efficacy and safety between dexmedetomedine and fentanyl for central venous catheter placement in pediatric intensive care unit (PICU)

Protocol summary

Study aim

Evaluation of efficacy and safety of dexmedetomidine for central venous catheter placement in pediatric intensive care unit compared to fentanyl

Design

Patients are divided into two groups 1 or 2 using random number generation software. Group 1 patients receive dexmededomedin intravenously at a dose of 1 mcg/kg for 10 minutes as a loading dose. Group 2 patients receive fentanyl at a dose of 1 mcg/kg for 10 minutes as a loading dose. For all patients during the catheter implantation, the infusion of these drugs is continued at a rate of 1 mcg/kg/hr. If sedation is insufficient (Ramsay Sedation Scale <4), the loading dose is repeated and the dose of drug infusion is doubled. In case of insufficient sedation for each patient, intravenous propofol is used at a dose of one mg per kg of body weight.

Settings and conduct

Pediatric intensive care unit of Sari Bu-Ali Sina Hospital

Participants/Inclusion and exclusion criteria

Children in need of central venous catheter placement in the pediatric intensive care unit age one month to 18 years old enter the study with the consent of the patient's guardian or guardian. Presence of bradycardia or hypotension, hypertension above 99% or apnea before the study, presence of cardiac conduction impairment in the ECG before drug administration, patients with ASA physical status classification IV, presence of renal failure, known heart failure, History of heart surgery and shock are excluded.

Intervention groups

Group 1: Children receiving dexmedetomidine for placement of central venous catheter Group 2: Children receiving fentanyl for placement of central venous catheter

Main outcome variables

1) Determining the amount of sedation during the catheterization process by Ramsay Sedation Scale 2) Changes in blood pressure, heart rate, respiration rate and O2 saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090813002342N10**
Registration date: **2020-09-05, 1399/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-05, 1399/06/15**
Update count: **0**

Registration date

2020-09-05, 1399/06/15

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-07, 1399/04/17

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety between dexmedetomedine and fentanyl for central venous catheter placement in pediatric intensive care unit (PICU)

Public title

Effect of dexmedetomedine and fentanyl in venous catheter placement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children one month to 18 years old who need a central venous catheter placement enter to study

Exclusion criteria:

bradycardia hypertension above 99% apnea before the study cardiac conduction impairment in the ECG before drug administration patients with ASA physical status classification IV renal failure known heart failure history of heart surgery shock

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

By simple randomization, individuals who meet the inclusion criteria and have completed informed consent will be assigned to two groups. This is done by assigning a random number to each person entering the study with random number generation software (using www.random.org). If it is an odd number, the patient will be allocated in group 1 and if it is even the patient will be assigned to group 2. The randomization process is performed by the ward supervisor (who is independent of the principal investigators). Randomization is performed before a patient enters the study and then the intervention is assigned according to his or her group therapy.

Blinding (investigator's opinion)

Double blinded

Blinding description

If a central catheter is needed, it will be announced by the treating physician. he trained nurse prepares dexmedetomidine and fentanyl according to the random code obtained (individual or even), respectively. The nurse, knowing the type of medicine, provides it to the doctor after diluting and homogenizing it in the same syringe. The physician performs the catheterization without knowing the type of drug, and the outcome assessor evaluates and records the sedation-related indicators under the physician's supervision. After completing the procedure and recording the outcomes (maximum 0.5-1 hour), the type of drug used is determined and recorded in the patient's file.

Placebo

Not 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

Payambar Azam Complex, 18 Km Farah Abad Blvd., Khazar Square, Sari, Mazandaran Province

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Province

Mazandaran

Postal code

4817844718

Approval date

2020-07-07, 1399/04/17

Ethics committee reference number

IR.MAZUMS.REC.1399.425

Health conditions studied

1

Description of health condition studied

Sedation in children for placement of a central venous catheter

ICD-10 code

Z45.2

ICD-10 code description

Encounter for adjustment and management of vascular access device

Primary outcomes

1

Description

Adequate sedation following the use of dexmedetomedine or fentanyl for central venous catheter placement

Timepoint
Before and at the end of the administration of the drug loading dose and then every 5 minutes until the end of catheter placement
Method of measurement
Ramsay Sedation Scale

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before and at the end of drug loading dose, then every 5 minutes until the end of catheter placement
Method of measurement
By digital monitoring device in PICU

2

Description
Heart rate
Timepoint
Before and at the end of drug loading dose, then every 5 minutes until the end of catheter placement
Method of measurement
By digital monitoring device in PICU

3

Description
Respiratory rate
Timepoint
Before and at the end of drug loading dose, then every 5 minutes until the end of catheter placement
Method of measurement
By digital monitoring device in PICU

4

Description
O2 saturation
Timepoint
Before and at the end of drug loading dose, then every 5 minutes until the end of catheter placement
Method of measurement
By digital monitoring device in PICU

Intervention groups

1

Description
Intervention group: Children receiving dexmedetomidine for placement of central venous catheter. Patients in this group receive dexmedetomidine intravenously at a dose of 1 mcg/kg for 10 minutes as a loading dose. Then during the catheter placement (nearly 0.5-1 hour), the infusion of these drugs is continued at a rate of 1 mcg/kg/hr. If sedation is insufficient (Ramsay Sedation Scale <4), the loading dose is repeated and the dose of drug infusion is doubled. In case of insufficient sedation for each patient, intravenous propofol is used at a dose of one mg per kg of body weight.
Category
Treatment - Drugs

2

Description
Control group: Children receiving fentanyl for placement of central venous catheter. Patients in this group receive fentanyl intravenously at a dose of 1 mcg/kg for 10 minutes as a loading dose. Then during the catheter placement (nearly 0.5-1 hour), the infusion of these drugs is continued at a rate of 1 mcg/kg/hr. If sedation is insufficient (Ramsay Sedation Scale <4), the loading dose is repeated and the dose of drug infusion is doubled. In case of insufficient sedation for each patient, intravenous propofol is used at a dose of one mg per kg of body weight.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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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
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
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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
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
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

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

For information on the details of the study without doing new statistical analysis

From where data/document is obtainable

Sending an email to mrrafati@mazums.ac.ir

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

The email will be checked if the request is clear and the information conditions are met Information is sent.

Comments