

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Impact of oral Clonidine on consumption of sedative agents in mechanically ventilated patients in pediatric intensive care unit

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Our goal is to investigate impact of Clonidine on level of sedative agents usage in mechanically ventilated children in PICU

Design

This randomized, double-blind, placebo-controlled, parallel-group and single center study will be conducted in PICU of Mofid Children`s Hospital, Tehran, Iran. Hundred children randomly divided in two groups , Treatment (No.1) and Control (No.2) by main administrator .

Settings and conduct

Randomized, double-blind, placebo-controlled, parallel-group and single center in Mofid Children`s Hospital, Tehran. Medical team (doctor and nurse) are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Children aged from 31 days to 15 years requiring ventilation for at least 3 days in PICU .
Exclusion criteria : Renal and hepatic failure ;
Gastrointestinal intolerance ; Severe neurological disorders ; Inotrope use ; Bradycardia and Hypotension .

Intervention groups

Participants will be randomized 1:1 to (group 1) fixed dose 5 µg/kg Clonidine every 6 hours via NGT(Abidi Pharmaceutical, Iran) plus variable dose 0.5 -2 µg/kg/hr Fentanyl and 0.05- 0.1 mg/kg Midazolam (titrated by Ramsay scale 2-3) or placebo (group 2) variable dose 0.5 - 2 µg/kg/hr Fentanyl and 0.05- 0.1 mg/kg Midazolam.(titrated by Ramsay scale 2-3)

Main outcome variables

Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170920036296N1**

Registration date: **2017-12-29, 1396/10/08**

Last update: **2017-12-29, 1396/10/08**

Update count: **0**

Registration date

2017-12-29, 1396/10/08

Registrant information

Name

Raha Khosravi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Pediatric pathology research center

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of oral Clonidine on consumption of sedative agents in mechanically ventilated patients in pediatric intensive care unit

Public title

Impact of Clonidine on children sedation in PICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with age of 31 days to 15 years requiring mechanical ventilation for 3 days.

Exclusion criteria:

Age

From **31 days** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind Patient and medical team are blinded. Only one of research team is not blinded and is in charge of data collection.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Behesti University of Medical Sciences

Street address

Evin

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2017-07-13, 1396/04/22

Ethics committee reference number

IR-SBMU.RETECH.REC.1396.347

Health conditions studied

1

Description of health condition studied

Sedation in PICU

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of Fentanyl dosage

Timepoint

Total Fentanyl dosage based on 0.5 - 2 mcg/kg/hr in 24 hours up to end of ventilator support .

Method of measurement

Ramsay Scale has 6 levels : level 1 anxious/agitated and level 6 deep sedation/ no response .Our goal is titrating Fentanyl to maintain patients on levels 2 - 3 (cooperative /respond to command) .

2

Description

Level of Midazolam dosage

Timepoint

Total Midazolam dosage based on 0.05 - 1 mg/kg in 24 hours up to end of ventilator support .

Method of measurement

Ramsay Scale has 6 levels : level 1 anxious/agitated and level 6 deep sedation/ no response .Our goal is titrating Midazolam to maintain patients on levels 2 - 3 (cooperative /respond to command) .

Secondary outcomes

1

Description

adverse effects

Timepoint

daily

Method of measurement

observation on signes and symotoms

Intervention groups

1

Description

Treatment group or group 1 : Clonidine with fixed dose 5 µg/kg every 6 hours via NGT(Abidi Pharmaceutical, Iran) plus with variable dose Fentanyl 0.5 - 2 µg/kg/hr and Midazolam 0.05 - 0.1 mg/kg .

Category

Treatment - Drugs

2

Description

Control group: In this group , placebo is administered

with variable dose Fentanyl 0.5 - 2 µg/kg/hr and
Midazolam 0.05 - 0.1 mg/kg .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children`s Hospital

Full name of responsible person

Sara Salarian

Street address

Shariati Ave , next to Mirdamad St.

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sarasalarian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Khodami

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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

Vice Chancellor for research of 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

Pediatric Critical Care Unit

Full name of responsible person

Dr. Raha Khosravi

Position

Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Pediatric Critical Care Unit

Full name of responsible person

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Position

Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr.Raha Khosravi

Position

Fellow

Latest degree

Subspecialist

Other areas of specialty/work

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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

Demographic and IPD collected for the primary outcome measure

When the data will become available and for how long

After publication

To whom data/document is available

All

Under which criteria data/document could be used

No condition

From where data/document is obtainable

Corresponding author

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

Sending email to Dr.Raha Khosravi
drarahakhosravi@yahoo.com

Comments