

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparrison of the effect of midazolam, fentanyl and their combination on the frequency of self-extubation among children admitted to the intensive care unit

Protocol summary

Summary

In this study, we want to find out which combination of medical treatments has a better analgesic and hypnotic effect on children admitted to the pediatric intensive care unit. This is a randomized, open-label, single center study on two hundred children admitted to pediatric ICU. Randomization in this study will be done using random numbers table. Patients will be allocated to three groups. Patients who have difficult airway or who are hemodynamically unstable would be excluded from the study. Interventions in this study include: Intervention group 1: Intravenous fentanyl alone at the dose of 1-3 mcg/kg/hour in order to keep the Ramsay score between 2 and 3 during the mechanical ventilation. Intervention group 2: this group receives Midazolam at the dose of 0.15 mg/kg/hour and intravenous fentanyl at the dose of 1-3 mcg/kg/hour in order to keep the Ramsay score between 2 and 3 during the mechanical ventilation. Control group: Intravenous Midazolam alone at the dose of 0.15 mg/kg/hour in order to keep the Ramsay score between 2 and 3 during the mechanical ventilation. The number of times that a child removes the ventilation tube and the number of days that the child is under ventilation are recorded and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611159475N2**

Registration date: **2017-02-12, 1395/11/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

Bahador Mirrahimi

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
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Recruitment status

Recruitment complete

Funding source

Pediatric Pathology Research Center, Shahid Beheshti
University of Medical Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparrison of the effect of midazolam, fentanyl and their combination on the frequency of self-extubation among children admitted to the intensive care unit

Public title

Comparison of the effect of midazolam, fentanyl, and combination of them on the frequency of self-extubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pediatric ICU patients who are under mechanical ventilation who have normal consciousness level. Exclusion criteria: difficult airway management defined as the airway with a structural abnormality including cleft palate and Pierre Robin syndrome; systemic disorders that affect intubation (Mucopolysaccharidosis); Mallampati score over 2; Patients with unstable hemodynamics.

Age

From **1 month** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

the randomization has been performed using random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak.

City

Tehran

Postal code

1985717434

Approval date

2015-10-16, 1394/07/24

Ethics committee reference number

IR.SBMU.RAM.REC.1394.253

Health conditions studied

1

Description of health condition studied

weaning from mechanical ventilation

ICD-10 code

Z51.8

ICD-10 code description

Other specified medical care

Primary outcomes

1

Description

Number of self extubation

Timepoint

during mechanical ventilation

Method of measurement

report

Secondary outcomes

1

Description

The number of days under mechanical ventilation

Timepoint

during hospitalization in intensive care unit

Method of measurement

report

Intervention groups

1

Description

Control group: Intravenous Midazolam alone at the dose of 0.15 mg/kg/hour in order to keep the Ramsay score between 2 and 3 during the mechanical ventilation.

Category

Treatment - Drugs

2

Description

Intervention group 1: Intravenous fentanyl alone at the dose of 1-3 mcg/kg/hour in order to keep the Ramsay score between 2 and 3 during the mechanical ventilation.

Category

Treatment - Drugs

3

Description

Intervention group 2: this group receives Midazolam at the dose of 0.15 mg/kg/hour and intravenous fentanyl at the dose of 1-3 mcg/kg/hour in order to keep the Ramsay score between 2 and 3 during the mechanical ventilation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's hospital

Full name of responsible person

Dr. Sara Salarian

Street address

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

City

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Other areas of specialty/work

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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

Dr. Seyed Ali Ziaee

Street address

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

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of medical sciences

Full name of responsible person

Dr. Sajad Razavi

Position

Associate Professor of Anesthesiology and critical care

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of medical sciences

Full name of responsible person

Dr. Sara Salarian

Position

Assistant Professor of Critical Care Medicine

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of medical sciences

Full name of responsible person

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Position

Asistant Profesor, Pharmacotherapy.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty