Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of using BiPAP and CPAP for successful weaning from the ventilator in children with underlying neurological problems admitted to the PICU

Protocol summary

Study aim

Knowledge of effectiveness of using BiPAP for successful weaning in children with underlying neurological problems admitted to the PICU of Motahari hospital can be helpful in patient management.

Design

Two arm parallel group randomised trial

Settings and conduct

As pilot,12 intubated patients, admitted to the PICU with underlying neurological disease will be included in each arm of the study. Randomization will be performed using Random Number Generation software. Inclusion criteria include intubation and underlying neurological disease, and exclusion criteria include having other associated underlying diseases. patients After meeting the conditions for weaning, such as consciousness and spontaneous breathing and the need for a low percentage of oxygen, weaning from the ventilator and immediately undergoing assisted breathing, Bilevel Positive Airway Pressure (BiPAP) or Continuous Positive Airway Pressure(CPAP) and were monitored for respiratory status for the next 72 hours.They are evaluated for the need of reintubation, and if there is no need for reintubation within 72 hours of extubation, the separation considered successful. Also duration of hospitalization of patients in two groups, as well as the associated complications, are evaluated. The rate of successful weaning considered as primary outcome and the duration of hospitalization and complications as the secondary outcome.

Participants/Inclusion and exclusion criteria

Inclusion: Intubation and having underlying neurological disease. Exclusion: Having other underlying diseases such as heart disease.

Intervention groups

Patients aged 1 month to 18 years who have underlying neurological disease and admitted to the PICU and are intubated. Of these, randomly 12 individuals will be placed under BiPAP after extubation and 12 randomly selected individuals will be placed under NCPAP. BiPAP , CPAP

Main outcome variables

Successful weaning

General information

Reason for update

Acronym

(CPAP)Bilevel Positive Airway Pressure(BiPAP), Continuous Positive Airway Pressur

IRCT registration information

IRCT registration number: **IRCT20250330065181N1**
Registration date: **2025-06-17, 1404/03/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-17, 1404/03/27**
Update count: **0**

Registration date

2025-06-17, 1404/03/27

Registrant information

Name

Tohid Ebadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3657 2318

Email address

tohid2ebadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of using BiPAP and CPAP for successful weaning from the ventilator in children with underlying neurological problems admitted to the PICU

Public title

Comparing the effectiveness of using BiPAP and CPAP for successful weaning from the ventilator in children with underlying neurological problems admitted to the PICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with underlying neurological disease. Children who are intubated.

Exclusion criteria:

Children with other underlying diseases such as heart disease.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using Random Number Generation software. Random generator is a simple software for generating random numbers between two specified numbers, where the discrete numbers are from 1 to 24 and each patient is identified by a number. First, the software randomly selects 12 numbers from 1 to 24, which are assigned to 12 intubated patients with underlying neurological problems and will be placed on BiPAP. The remaining 12 numbers from 1 to 24 will be assigned to other intubated patients with neurological problems and will be placed on CPAP. Now, patients are assigned numbers one to 24 in order of admission and are put on BiPAP or CPAP. For example, initially according to the software, we have 12 numbers that are supposed to be put on BiPAP, for example, numbers 3,4,7,11,13,14,... Now, the first patient with the entry criteria will be number one and will be put on CPAP. The next patient is assigned number 2 and is put on CPAP. The next patient is assigned number 3 and is put on BiPAP, and so on, up to 24 patients.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences Ethics Committee

Street address

No 11, Borujerdi Street

City

Urmia

Province

West Azarbaijan

Postal code

5713147454

Approval date

2024-12-21, 1403/10/01

Ethics committee reference number

IR.UMSU.REC.1403.282

Health conditions studied

1

Description of health condition studied

Neurological diseases

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

Successful extubation

Timepoint

72 hours after extubation

Method of measurement

Information collection form

Secondary outcomes

1

Description

Complications of intubation

Timepoint
72 hours after extubation
Method of measurement
Information collection form

Intervention groups

1

Description
Control group: 12 intubated patients with underlying neurological disease, who were randomly selected, were weaned from the ventilator after meeting the conditions and immediately underwent Continuous Positive Airway Pressure(CPAP), respiratory assistance, using an anatomical face mask and were monitored for 72 hours for the need for re-intubation.
Category
Treatment - Other

2

Description
Intervention group: 12 Intubated patients with underlying neurological disease, who were randomly selected, were weaned from the ventilator after meeting the conditions and immediately underwent Bilevel Positive Airway Pressure(BiPAP), respiratory assistance, using an anatomical face mask and were monitored for 72 hours for the need for re-intubation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari hospital, Urmia
Full name of responsible person
Tohid Ebadi
Street address
No11, Borujerdi street
City
Urmia
Province
West Azarbaijan
Postal code
5713147454
Phone
+98 44 3657 2318
Email
Tohid2ebadi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber Golizade
Street address
Resalat Boulevard, Emergency Alley
City
Urmia
Province
West Azarbaijan
Postal code
5713147454
Phone
+98 44 3657 2318
Email
Tohid2ebadi@gmail.com
Grant name
0
Grant code / Reference number
0
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Tohid Ebadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Borujerdi
City
Urmia
Province
West Azarbaijan
Postal code
5713147454
Phone
+98 44 3657 2318
Email
Tohid2ebadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Tohid Ebadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Borujerdi

City
Urmia

Province
West Azarbaijan

Postal code
5713147454

Phone
+98 44 3657 2318

Email
Tohid2ebadi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Tohid Ebadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Borujerdi

City
Urmia

Province
West Azarbaijan

Postal code
5713147454

Phone
+98 44 3657 2318

Email
Tohid2ebadi@gmail.com

Sharing plan

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

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Successful extubation rate

When the data will become available and for how long
1 Mon

To whom data/document is available
Mohammad Salavatizade, Mohammad Valizade, Babak Hasanlooyi, Tohid Ebadi

Under which criteria data/document could be used
After statistical analysis

From where data/document is obtainable
Tohid Ebadi

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

Comments