

# 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 Pressure

##### 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

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**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

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Borujerdi

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## 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

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## 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**

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**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**

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**