Clinical Trial Details (PDF Generation Date :- Fri, 12 May 2023 07:21:36 GMT)

CTRI Number	CTRI/2019/12/022328 [Registered on: 12/12/2019] - **Trial Registered Prospectively**
Last Modified On	11/12/2019
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Other (Specify) [Ventilation weaning strategy]
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A RANDOMISED CONTROLLED TRIAL COMPARING TWO METHODS OF EXTUBATOON READINESS TRIAL (CPAP AND PRESSURE SUPPORT) IN MECHANICALLY VENTILATED CHILDREN
Scientific Title of Study	PRESSURE SUPPORT VERSUS CPAP FOR EXTUBATION READINESS IN CHILDREN RECEIVING MECHANICAL VENTILATION: A RANDOMIZED CONTROLLED TRIAL

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Karthi N
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Details Contact Person (Scientific Query)

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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> PGIMER, Chandigarh

Primary Sponsor

Primary Sponsor Details	
Name	PGIMER Chandigarh
Address	PGIMER, Sector 12, Chandigarh, 160012
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Vishwa CR	Postgraduate Institute of Medical Sciences and Research, Chandigarh	Department of Paediatric Critical Care, Paediatric Department Office, 3rd Floor, Advanced Paediatric Center, PGIMER Chandigarh CHANDIGARH	8800517848 drvishwacr@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
INSTITUTE ETHICS COMMITTEE	Approved	14/11/2019	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Diseases of the respiratory system

Intervention / Comparator Agent

Type	Name	Details
Intervention	Pressure Support	A mode used for extubation readiness test - 2 hours
Comparator Agent	CPAP	A mode used for extubation readiness test - 2 hours

Inclusion Criteria

Inclusion Criteria	
Age From	1.00 Month(s)
Age To	12.00 Year(s)
Gender	Both
Details	1. Children aged 12 years or younger and receiving mechanical ventilation at least for 48 hours 2. Informed written consent

Exclusion Criteria

Exclusion Criteria	
Details	1. Procedural or short term intubation 2. End of life care 3. Neuromuscular disorders requiring slow or customised weaning plan 4. Prolonged mechanical ventilation >4 weeks

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Successful extubation after first extubation readiness test	72 hours post extubation

Secondary Outcome

Outcome	Timepoints
Rate of re-intubation	72 hours post extubation
Need for post extubation NIV	72 hours post extubation
Ventilation free days	Till discharge from PICU
Length of PICU stay	Till discharge from PICU

Target Sample Size	**Total Sample Size=**244 **Sample Size from India=**244 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	12/12/2019
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**2 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Nil
Brief Summary	This is a single centre randomised controlled study at a tertiary centre in North India. Children will be randomised to CPAP or Pressure support for extubation readiness trial. The primary outcome is rate of successful extubation after first ERT. Secondary outcomes include rate of re-intubation, need for post extubation NIV, ventilation free days and length of PICU stay.