

Noninvasive Continuous Positive Airway Pressure (CPAP) by a new pediatric helmet in infants with acute respiratory failure: A comparison with standard full face mask CPAP system

Submission date 30/06/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/10/2021	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

01

Study information

Scientific Title

Noninvasive Continuous Positive Airway Pressure (CPAP) by a new pediatric helmet in infants with acute respiratory failure: A comparison with standard full face mask CPAP system

Acronym

HCPAP

Study objectives

Noninvasive continuous positive airway pressure represents a safe and effective means of treating cooperative patients with acute respiratory failure, improving gas exchange, and reducing the rate of complications related to conventional mechanical ventilation. However, the choice of the interface is one of the crucial issues affecting treatment outcome in pediatric age and in particular in preschool children in whom intolerance frequently compromise non-invasive respiratory treatment. The most common interfaces used in infants and children are nasal prongs and facial masks. The most important principle in guiding the selection of an interface is that it should fit comfortably. However, while the nasal masks can leak gas when the infant opens its mouth, the facial masks can cause significant gastric distension and a tendency for infants to vomit, with the potential risk of aspirating gastric contents. The various complications such as air leaks, skin irritation on the bridge of the nose, and discomfort reported with nasal or facial masks in children frequently lead to interruption of the ventilatory treatment. Thus, improving the interface between the patient and the ventilator would be expected to facilitate longer, more effective application of non-invasive respiratory support ventilation. A new small helmet designed for young infants has been recently introduced to administer Continuous Positive Airway Pressure (CPAP). The purpose of this study was to investigate the effectiveness of helmet CPAP in terms of tolerance and gas exchange as an alternative to more conventional CPAP full face mask system in infants needing continuous positive airway pressure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee at Mangiagalli and Queen Elena Hospital Foundation (c/o Dr Isabella Damilano), approved on 21 December 2005.

Study design

Prospective, randomized physiological cross-over study that included within-participant comparison.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute respiratory failure, hypoxemic

Interventions

Each infant was randomized to treatment with either helmet or mask CPAP (duration: 90 min). Then the infant was treated with the other CPAP (i.e. those who had been treated with helmet CPAP in the initial phase of the trial were then treated with mask CPAP in the second phase, and vice versa). Each CPAP trial phase was preceded by a 30 min unassisted spontaneous breathing period on oxygen therapy delivered by the Venturi mask.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Tolerance

Secondary outcome measures

1. Gas exchange
2. Respiratory effort

Overall study start date

01/01/2007

Completion date

01/01/2009

Eligibility

Key inclusion criteria

Acute respiratory distress including the following:

1. $\text{PaO}_2:\text{FiO}_2 < 300$ mmHg
2. Bilateral lung infiltrates on chest x-ray
3. Age < 2 years

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

20

Total final enrolment

20

Key exclusion criteria

1. Underlying chronic lung disease, such as bronchopulmonary dysplasia and cystic fibrosis
2. Inability to clear major tracheal secretions
3. Requirement for emergency intubation including persistent apnea or cardiopulmonary resuscitation
4. Cardiac disease
5. Presence of more than two new organ failures
6. Tracheostomy
7. Coma
8. Recent orogastric surgery

Date of first enrolment

01/01/2007

Date of final enrolment

01/01/2009

Locations**Countries of recruitment**

Italy

Study participating centre

via della Commenda 9

Milan

Italy

20122

Sponsor information**Organisation**

Mangiagalli and Queen Elena Hospital Foundation (Italy)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.policlinico.mi.it/>

ROR

<https://ror.org/016zn0y21>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Internally funded by the Mangiagalli and Queen Elena Hospital Foundation (Italy)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/07/2010	28/10/2021	Yes	No