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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

Registration date
30/07/2007

Overall study status
Completed

Last Edited
28/10/2021

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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-partecipant 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. PaO2:FiO2 <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. Tecent 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