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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

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| **Submission date**<br>30/06/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>30/07/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>28/10/2021 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
Tolerance

### Key secondary outcome(s))
1. Gas exchange
2. Respiratory effort

### 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

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex
All

### 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)

**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

**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 |