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# Randomised controlled trial of Bubble CPAP versus infant flow driver for successful extubation in preterm infants

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| **Submission date**<br>29/09/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>29/09/2006 | **Overall study status**<br>Completed | |
| **Last Edited**<br>15/04/2009 | **Condition category**<br>Neonatal Diseases | |

**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**
N0227165400

# Study information

### Scientific Title

### Study objectives
To compare the efficacy and safety of two different systems of delivering nasal continuous positive airway pressure for successful extubation of preterm infants.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### 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
Neonatal Diseases: Respiratory

### Interventions
Babies up to 30 week gestation and requiring ventilatory support would be eligible for study pre-extubation. Signed informed parental consent will be sought before randomisation.Babies will be randomised onto one of the currently used CPAP modes: Infant Flow Driver or Bubble CPAP. Nursing care including monitoring will be as per unit protocols. The successful extubation (primary outcome) will be analysed as per pre-defined clinical and physiological criteria. Each group will be analysed based on duration of ventilation (less than and equal to 2 weeks, and more than 2 weeks). Total number of babies required will be 59 each group.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Respiratory failure within 72 hours defined as:
1. Need for re-intubation primarily for respiratory distress AND/OR
2. Uncompensated Respiratory Acidosis (pH<7.2 AND pCO2>8kPa

### Secondary outcome measures
1. Endotracheal reintubation
2. Duration of CPAP days
3. Chronic Lung Disease, Morbidity, Mortality and Data on complications including gastrointestinal will be collected.

### Overall study start date
01/10/2004

### Completion date
30/06/2007

## Eligibility

### Key inclusion criteria
1. Born between 24 and less than 30 weeks gestation, or with a birth weight of 600 to 1500 grams
2. Endotracheal intubation for any duration
3. Stable or improving respiratory status with inspired oxygen concentration of less than 50%
4. First extubation attempt
5. Signed parental consent
6. Considered ready for extubation by the clinical management team

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Both

### Target number of participants
Total number of babies required will be 59 each group

### Key exclusion criteria
1. Major congenital malformations, which are known to adversely affect life expectancy
2. Known congenital or acquired upper airway obstruction
3. Neuromuscular disorders

### Date of first enrolment
01/10/2004

### Date of final enrolment
30/06/2007

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**South Tees Hospital Trust**
Middlesbrough
United Kingdom
TS4 3BW

# Sponsor information

### Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

### Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

### Sponsor type
Government

### Website
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

### Funder type
Government

### Funder Name
South Tees Hospitals NHS Trust (UK)

**Funder Name**
NHS R&D Support Funding (UK)

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### 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 | results | 01/05/2009 | | Yes | No |