ISRCTN83339638 https://doi.org/10.1186/ISRCTN83339638

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

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

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
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
1. Endotracheal reintubation
2. Duration of CPAP days
3. Chronic Lung Disease, Morbidity, Mortality and Data on complications including gastrointestinal will be collected.

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

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