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		
Registration date 29/09/2006	Overall study status Completed	[] Statistical analysis plan		
		[X] Results		
Last Edited 15/04/2009	Condition category Neonatal Diseases	Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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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 preextubation. 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