

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 ☒ 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

Contact name

Dr Samir Gupta

Contact details

South Tees Hospital Trust
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

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

Primary study design

Interventional

Study design

Randomised controlled trial

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 ($\text{pH} < 7.2$ AND $\text{pCO}_2 > 8\text{kPa}$)

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