

Nasal biphasic positive airway pressure vs. nasal continuous positive airway pressure following extubation in infants less than 30 weeks gestation

Submission date 07/06/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 07/06/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/10/2018	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 Suresh Victor

Contact details
St Mary's Hospital
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL
-
suresh.victor@cmft.nhs.uk

Additional identifiers

Protocol serial number
10146

Study information

Scientific Title

A randomised controlled trial of nasal biphasic positive airway pressure vs. nasal continuous positive airway pressure following extubation in infants less than 30 weeks gestation

Acronym

EXTUBATE

Study objectives

Babies born prematurely have breathing difficulties for which they need support from a machine called ventilator. The ventilator gives them regular breaths through a breathing tube placed in the wind pipe. The process of removing the tube or extubation and allowing the baby to breathe on his/her own does not always go to plan. Around one-fourth of babies need to have the breathing tube replaced in the wind pipe. The process of replacing the tube can be traumatic and spending more time on the ventilator can damage the baby's immature lungs. Continuous Positive Airway Pressure (n-CPAP) and Biphasic Positive Airway Pressure (n-BiPAP) are ways of supporting breathing that are less invasive - they use tubes that go only a few millimetres into the nostril. n-CPAP produces a constant pressure at the nose that is transmitted to the lungs. n-BiPAP produces a constant pressure and also gives extra breaths. We want to find out if these extra breaths will give the baby the added support needed to stay off the ventilator.

We will conduct a randomised trial at several regional centres in the north-west of England. Babies born before 30 weeks gestation and less than two weeks old will be eligible to participate in the study. We will randomly assign babies to receive either n-CPAP or n-BiPAP to see which of these devices allows the baby to breathe most comfortably and stay off the ventilator.

Early and successful extubation would mean that premature babies will spend less time on the ventilator. This will reduce the chances of injury to the baby's lungs and allow for more efficient use of intensive care cots at referral centres. It would also mean that babies can be moved earlier to centres closer to home.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West 11 Research ethics committee, Preston approved on 4th Jan 2011, 10/H1016/145

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Not specified

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Reproductive Health and Childbirth, Generic Health Relevance and Cross Cutting Themes;
Subtopic: Reproductive Health and Childbirth (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Reproductive Health & Childbirth, Paediatrics

Interventions

BiPAP: The BiPAP group will receive at extubation a mean airway pressure of 6 cm water (positive end expiratory pressure of 4 cm water and peak inspiratory pressure of 8 cms of water). Inspiratory time of one second and respiratory rate of 30/ min will always be maintained.

CPAP: The CPAP group will receive at extubation a single level continuous positive airway pressure of 6 cm water for at least 48 hours before weaning is commenced.

Study Entry: Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Extubation Failure; Timepoint(s): This will be defined as: Uncompensated respiratory acidosis defined as pH less than 7.2

Key secondary outcome(s)

1. Maintenance of successful extubation for 7 days
2. Total days on ventilator, n-CPAP/ n-BiPAP
3. Number of ventilator days following first extubation attempt
4. Oxygen requirement at 28 days of age and at 36 weeks of corrected gestation
5. pH, partial pressure of carbon dioxide in the first post extubation gas
6. Duration of hospitalisation
7. Rates of abdominal distension requiring cessation of feeds for 7 days post extubation
8. Rate of apnoea and bradycardia expressed as events per hour during the 48 hours following extubation
9. Age at transfer back to referral centre in days

Completion date

31/03/2014

Eligibility

Key inclusion criteria

1. Born before 30 weeks gestation
 2. Ventilated through an endotracheal tube
 3. Less than two weeks old
 4. First attempt at extubation
- Target Gender: Male & Female; Upper Age Limit 30 weeks ; Lower Age Limit 23 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Presence of major congenital malformations
2. Presence of neuromuscular disease
3. Presence of known upper respiratory tract abnormalities
4. Likely to be within 7 days post-operative
5. Presence of intraventricular haemorrhage with parenchymal extension

Date of first enrolment

01/04/2011

Date of final enrolment

31/03/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

St Mary's Hospital

Manchester

United Kingdom

M13 9WL

Sponsor information**Organisation**

Central Manchester University Hospitals NHS Trust (CMFT) (UK)

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK)- Research for Patient Benefit Grant

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	01/08/2016		Yes	No
Protocol article	protocol	09/12/2011		Yes	No