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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

Registration date
07/06/2011

Overall study status
Completed

Last Edited
08/10/2018

Condition category
Neonatal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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 babys 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 babys 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

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2011

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

Age group
Neonate

Sex
Both

Target number of participants
Planned Sample Size: 540; UK Sample Size: 540;

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
England

United Kingdom

Study participating centre

St Mary's Hospital
Manchester
United Kingdom
M13 9WL

Sponsor information

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

Sponsor details
St Mary's Hospital
Manchester Royal Infirmary
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Sponsor type
Hospital/treatment centre

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

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