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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
07/06/2011		[X] Protocol		
<b>Registration date</b> 07/06/2011	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 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

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### Contact details

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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 Oxford Road Manchester England United Kingdom M13 9WL

### 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?
<u>Protocol article</u>	protocol	09/12/2011		Yes	No
Results article	results	01/08/2016		Yes	No