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Biphasic nasal continuous positive airway pressure (CPAP) versus nasal CPAP at extubation

Submission date 12/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/10/2010	**Overall study status** Completed	
Last Edited 21/08/2020	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
L09030A

Study information

Scientific Title

Prospective randomised controlled trial comparing biphasic nasal continuous positive airway pressure (BiPAP) versus nasal continuous positive airway pressure (NCPAP) at extubation of preterm babies

Acronym
BiPAP study

Study objectives
The aim of this study is to find out whether two levels of supportive airway pressure (biphasic continuous positive airway pressure [BiPAP]) is better at preventing the baby going back to needing reintubation and mechanical ventilation (avoiding extubation failure) compared to a single level of supportive airway pressure (nasal continuous positive airway pressure [NCPAP]) in preterm babies being taken off (extubated) mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Regional Ethics Committee (REC) 1, 29/04/2010, ref: 10/S0703/9

Study design
Prospective open label randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory distress in preterm babies; Neonatology

Interventions
Use of Biphasic CPAP or nasal CPAP (based on randomisation) soon after the baby is extubated from mechanical ventilation. Period of intervention first 72 hours post-extubation.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Successful extubation, defined as not meeting reintubation/extubation failure criteria until 72 hours after extubation

Key secondary outcome(s))
1. Gastrointestnal (GI) complications
2. Total duration on ventilatory support
3. Incidence of Chronic Lung Disease (CLD) (defined as need for oxygen support beyond 28 days

/36 weeks corrected gestational age)
4. Incidence and severity of intraventricular haemorrhage (IVH)
5. Time to full feeds

Completion date
30/08/2014

Eligibility

Key inclusion criteria
Babies born between 23 weeks and 0 days and 30 weeks and 6 days gestation who are supported with mechanical ventilation for at least 6 hours in the first 28 days of life (first episode of ventilation only)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
122

Key exclusion criteria
Babies with any factor that may affect respiratory effort evident from the initial period, e.g.:
1. Neonatal encephalopathy (involvement of the brain with possible seizures, hypoxic ischaemic encephalopathy [HIE] stage 2 or 3, which is related to perinatal asphyxia)
2. Obvious major birth defects (congenital malformations)
3. Disorders of the muscular system with significant weakness (neuromuscular problems)

Date of first enrolment
01/09/2010

Date of final enrolment
30/08/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Consultant Neonatologist
Wishaw
United Kingdom
ML2 0DP

Sponsor information

Organisation
NHS Lanarkshire (UK)

ROR
https://ror.org/049prb569

Funder(s)

Funder type
Other

Funder Name
Not provided at time of registration

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	29/05/2019	21/08/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes