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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

Contact name
Dr Sridhar Kalyanasundaram

Contact details
Consultant Neonatologist
Department of Neonatology
Wishaw General Hospital
50 Netherton street
Wishaw
United Kingdom
ML2 0DP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Separate document, approved by ethics committee (no link available now)

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 measure
Successful extubation, defined as not meeting reintubation/extubation failure criteria until 72 hours after extubation

Secondary outcome measures
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

Overall study start date
01/09/2010

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

Age group
Neonate

Sex
Both

Target number of participants
120 babies

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
Scotland

United Kingdom

Study participating centre
Consultant Neonatologist
Wishaw
United Kingdom
ML2 0DP

Sponsor information

Organisation
NHS Lanarkshire (UK)

Sponsor details
c/o Mr Raymond Hamill
R&D Manager
Monklands Hospital
Monkscourt Avenue
Airdrie
United Kingdom
ML6 8LL

Sponsor type
Government

Website
http://www.nhslanarkshire.org.uk/Pages/default.aspx

ROR
https://ror.org/049prb569

Funder(s)

Funder type
Other

Funder Name
Not provided at time of registration

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?
Results article	results	29/05/2019	21/08/2020	Yes	No