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Which is the most effective method of providing non-invasive respiratory support (NIRS) to preterm neonates with lung disease?

Submission date 24/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/06/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/08/2016	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

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

6532

Study information

Scientific Title
Which is the most effective method of providing non-invasive respiratory support (NIRS) to preterm neonates with lung disease?

Acronym
NIRS

Study objectives
Non-invasive respiratory support (NIRS) is being required by increasing numbers of infants in UK neonatal units. Because of the disadvantages of intermittent positive pressure ventilation (IPPV), it is important to optimise practice so that as many infants as possible can be supported non-invasively - either completely, or after an initial short period of IPPV.

A number of devices are available to provide NIRS. Three of the most widely used are CPAP, SiPAP and Optiflow. There is therefore an urgent need to compare the effectiveness of these three modes of NIRS. Although ultimately a large multicentre clinical trial will be needed, the logical and ethical first step is to compare their short-term effectiveness in a pilot study using a combination of clinical and physiological end-points. Such a study, would provide important data in itself to guide clinical practice, but would also provide essential preliminary data to design a definitive clinical trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 08/H1111/18)

Study design
Single centre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

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

Interventions
Group 1: Continuous positive airway pressure (CPAP) versus synchronised inspiratory positive airway pressure (SiPAP)
Group 2: CPAP versus Optiflow

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Provide evidence to allow clinicians to choose the most effective mode of NIRS

Secondary outcome measures
1. Allow standardisation of NIRS equipment and policies across neonatal care networks
2. Optimise work of breathing allowing infants to thrive and wean off NIRS more rapidly
3. Potentially reduce incidence and/or severity of neonatal chronic lung disease, with consequent savings in health care in early life (e.g., home oxygen)
4. Provide information to guide clinicians and managers in purchasing cost-effective equipment
5. Reduce cot days on IPPV allowing more efficient use of resources
6. Reduce likelihood of infant having to be reintubated to receive IPPV

Overall study start date
01/11/2008

Completion date
01/11/2009

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2008

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medical Research Building
Brighton
United Kingdom
BN1 9PS

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust (UK)

Sponsor details
Royal Sussex County Hospital
Eastern Road
Brighton
England
United Kingdom
BN2 5BE

Sponsor type
Hospital/treatment centre

Website
http://www.bsuh.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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