

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

Protocol serial number
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)

Primary study design

Interventional

Study design

Single centre randomised interventional treatment trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

01/11/2009

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Medical Research Building

Brighton

United Kingdom

BN1 9PS

Sponsor information

Organisation

Brighton and Sussex University Hospitals NHS Trust (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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration