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Optimisation of invasive breathing support in newborns by continuous carbon dioxide monitoring

Submission date
29/10/2018

Recruitment status
No longer recruiting

Registration date
01/11/2018

Overall study status
Completed

Last Edited
18/10/2022

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many prematurely born infants, and a small number of those born at term, will require help with their breathing in the newborn period. A breathing tube connected to a ventilator (mechanical ventilation) can be life saving, but unfortunately it can be associated with long-term complications. The most common of these adverse outcomes is chronic lung disease, yet infants can also have neurological problems at follow up and may develop cerebral palsy. These complications are increased in infants who have suffered abnormalities in their carbon dioxide levels. Therefore, if we are to improve the outcomes of infants requiring breathing support in the newborn period, it is vital that we can appropriately and safely monitor these levels. By having a real time continuous reading of carbon dioxide we aim to be able to reduce the number of acute complications of respiratory support by allowing earlier detection of blocked or dislodged breathing tubes. We also aim to be able to reduce the number of invasive blood tests performed, which would normally be used to monitor carbon dioxide levels when continuous monitoring is not available. Finally by having continual monitoring of carbon dioxide levels available we aim to be able to regulate these values more closely to avoid levels that are either too high, or too low, the results of which may lead to the adverse outcomes mentioned above.

Who can participate?
Newborns requiring invasive mechanical ventilation within the newborn period

What does the study involve?
The research team will be approaching parents within the first day of admission to the neonatal unit to discuss the study and obtain informed written consent if parents wish for their baby to take part. The study will involve inserting a small CE marked device into the routine ventilator circuit so that the levels of carbon dioxide produced can be continuously monitored.

What are the possible benefits and risks of participating?
This device is aimed at improving newborn safety whilst infants are receiving life saving

breathing support, therefore participants may benefit from the use of this device. As this study is non invasive and uses a CE trademarked device, there are no known risks to participants taking part.

Where is the study run from?
King’s College Hospital Neonatal Unit, London (UK)

When is the study starting and how long is it expected to run for?
October 2018 to December 2021

Who is funding the study?
1. The Charles Wolfson Charitable Trust (UK)
2. SLE Ltd (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39771

Study information

Scientific Title
Optimising mechanical ventilation in newborns using capnography

Study objectives
1. Using end tidal capnography will allow earlier detection of acute complications in mechanically ventilated infants such as blocked or dislodged endotracheal tubes.
2. End tidal capnography will reduce the average daily frequency of invasive blood sampling and hence the associated complications related to blood transfusions.
3. Using side stream capnography to provide continuous monitoring will reduce the time spent with abnormal carbon dioxide levels and the development of serious complications such as bronchopulmonary dysplasia, intraventricular haemorrhage and periventricular leukomalacia.
4. Accurate calculation of anatomical and alveolar dead space in infants with various neonatal respiratory diseases using real time capnography will allow appropriate tidal volumes to be delivered in different respiratory conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/11/2018, London-Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; 0207 104 8018; nrescommittee.london-camdenandkingscross@nhs.net) ref: 18/LO/1602

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Mechanical ventilation in newborns

Interventions
A side stream capnograph will be integrated with the ventilator circuit for the whole time the infant is receiving invasive mechanical ventilation. In order to validate the side steam

capnography against the gold standard mainstream capnography, the NM3 mainstream capnograph will be incorporated into the ventilator circuit for a 20 minute period.
Infants will have routine neonatal follow up as per the clinical team and no follow up specific to the research being carried out is required.

Intervention Type
Device

Primary outcome measure
Decrease in the complications of mechanical ventilation and decrease in the frequency of blood sampling in ventilated newborn infants.; Timepoint(s): .
The following are recorded throughout the period the infant is receiving invasive mechanical ventilation:
1. Frequency of complications of mechanical ventilation (pneumothorax, blocked or dislodged endotracheal tube, hypo or hypercarbia),
2. Frequency of routine blood gas sampling
These will be compared to historical controls who were invasively mechanically ventilated prior to the use of routine end tidal capnography monitoring.

Secondary outcome measures
1. Validation of side stream capnography with mainstream capnography and arterial carbon dioxide levels, ascertained by correlation of values in kPa during a twenty-minute validation period
2. Anatomical and alveolar dead space, calculated in mechanically ventilated infants with four neonatal respiratory conditions:
2.1. Respiratory distress syndrome
2.2. Evolving bronchopulmonary dysplasia
2.3. Meconium aspiration syndrome
2.4. Persistent pulmonary hypertension of the newborn
These will be calculated by analysing carbon dioxide waveforms using the Bohr/Enghoff equation once the infant is no longer receiving mechanical ventilation.

Overall study start date
01/10/2018

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Neonates
2. Invasively mechanically ventilated
3. Admitted to the neonatal intensive care unit
4. Written parental consent

Participant type(s)
Patient

Age group

Neonate

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment
92

Key exclusion criteria
1. Non ventilated infants
2. Infants on non-invasive respiratory support

Date of first enrolment
28/11/2018

Date of final enrolment
14/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Neonatal Intensive Care Unit
4th Floor Golden Jubilee Wing
King's College Hospital
Denmark Hill
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Sponsor information

Organisation
King's College Hospital

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Sponsor type
Hospital/treatment centre

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Sponsor type
University/education

Funder(s)

Funder type
Charity

Funder Name
Charles Wolfson Charitable Trust

Funder Name
SLE LIMITED

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Results are intended to be published one year after the completion of the trial. Results will also be presented at national and international conferences.

Intention to publish date
31/08/2022

Individual participant data (IPD) sharing plan
The datasets analysed will be expected to be included in the subsequent results publication but full data sharing plans for the current study are not currently known and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2020	25/01/2022	Yes	No
Results article		18/02/2021	25/01/2022	Yes	No
Results article		01/07/2021	25/01/2022	Yes	No
Protocol file	version 1	06/08/2018	18/10/2022	No	No
HRA research summary			28/06/2023	No	No