ISRCTN17041826 https://doi.org/10.1186/ISRCTN17041826

Optimisation of neonatal ventilation

Submission date 07/07/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 11/07/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 10/10/2022	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Premature babies are at high risk of developing breathing problems because their lungs are not fully matured when they are born. The use of mechanical ventilation (breathing machine) is life saving for these children, however it can also damage the lungs, leading to long-term breathing problems or dependence on receiving oxygen (bronchopulmonary dysplasia). New forms of breathing support for newborn babies have been developed with the aim of minimising lung damage. One of these new forms, called volume targeted ventilation (VTV), delivers the same size of inflation (mechanical breath) to the baby despite changes in their lung function. Previous studies in both prematurely and term-born infants that larger rather than smaller mechanical breaths appear to reduce the breathing effort required from the baby. However it is no known what size of inflation is best for the growing population of prematurely born infants with developing or established bronchopulmonary, who may remain on the breathing machine for many months. The aim of this study is to assess how hard premature babies on breathing support are working to breathe when receiving different breath volumes (sizes) via the ventilator (within the normal baby breathing range).

Who can participate?
Infants born at least eight weeks early who rely on breathing machines two weeks after birth.

What does the study involve?
Each baby has a small catheter (thin flexible tube) placed to measure how hard the baby is working to breathe. The babies then receive four different sizes of breath for 20 minutes in a random order, with 20 minutes in between (during which they receive their normal size breaths from the ventilator). The work or breathing is measured for the last 5 minutes of each period. The whole study takes around 3 hours, after which the catheter is removed. The best mechanical breath size is determined by the level at which the baby has the lowest work of breathing.

What are the possible benefits and risks of participating?
There are no direct benefits to participants taking part in this study. There is a small risk of slight discomfort for participants when the catheter is placed and removed.

Where is the study run from?
King's College Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to February 2018

Who is funding the study?
1. Biomedical Research Council (UK)
2. Kings College London (UK)

Who is the main contact?
Professor Anne Greenough
anne.greenough@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Anne Greenough

ORCID ID
http://orcid.org/0000-0002-8672-5349

Contact details
King's College London
Neonatal Unit
4th Floor
Golden Jubilee Wing
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS
+44 20 3299 9000 ext. 38492
anne.greenough@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20699

Study information

Scientific Title
Optimisation of neonatal ventilation - determining the appropriate level of volume guarantee

Study objectives
The aim of this study is to determine which level of volume targetting will best reduce the work of breathing in ventilated infants with evolving or established bronchopulmonary dysplasia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board - South East Coast - Surrey Research Ethics Committee, 28/10/2015, ref: 15/LO/1414

Study design
Single-centre randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Specialty: Children, Primary sub-specialty: Neonatal

Interventions
Participants are ventilated infants who are randomised to receive targeted tidal volume of 4,5,6, and 7ml in a random order for 20 minutes, with a 20 minute 'washout period' of their baseline settings in between. A dual tipped pressure transducer catheter is inserted at the beginning of the study (similar to a feeding tube) and used to record the pressure-time product of the diaphragm for the last 5 minutes of each 20 minute period. The study lasts for around 3 hours in total.

Intervention Type
Other

Primary outcome measure
Work of breathing, measured as the pressure-time product of the diaphragm, during the last 5 minutes of each 20 minute period at different levels of volume targeting.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2015

Completion date
28/02/2018

Eligibility

Key inclusion criteria
2. Infants born less than 32 weeks completed gestation
2. Remain ventilator dependent two weeks after birth

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 18; UK Sample Size: 18

Total final enrolment
18

Key exclusion criteria
1. Infants born above 32 weeks of gestational age
2. Infants who have been successfully extubated by two weeks age
3. Complex congenital cardiac abnormalities
4. Congenital diaphragmatic hernia

Date of first enrolment
04/05/2016

Date of final enrolment
14/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College London

Sponsor details
Room 1.8 Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Biomedical Research Council

Funder Name
Kings College London

Alternative Name(s)
King's College, King's College London UK, KCL, King's

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
14/11/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		08/02/2019		No	No
Results article	results	01/01/2019	08/05/2019	Yes	No
Protocol file	version 3.0	16/08/2016	10/10/2022	No	No
HRA research summary			28/06/2023	No	No