

Optimisation of neonatal ventilation

Submission date 07/07/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/07/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Respiratory	<input type="checkbox"/> 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 not 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

King's College Hospital

Denmark Hill

London

United Kingdom

SE5 9RS

Sponsor information**Organisation**

King's College London

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

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?
Results article	results	01/01/2019	08/05/2019	Yes	No
Basic results		08/02/2019		No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	16/08/2016	10/10/2022	No	No