# Optimisation of neonatal ventilation

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

## 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**

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