

Volume Guarantee or Volume-Controlled ventilation

Submission date 02/09/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/10/2020	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Premature babies often show signs of respiratory distress syndrome (breathing difficulties) after they are born. Their lungs are immature and stiff which means babies find it difficult to breathe properly. We have different ways of treating this according to each baby's needs, including supporting their breathing using an artificial breathing machine (a ventilator). A ventilator delivers a volume of gas (mixture of air and oxygen) to the baby's lungs for each breath.

This study aims to compare two types of ventilation, Volume Guarantee and Volume-Controlled ventilation, which control the volume of gas reaching a baby in different ways. In Volume Guarantee, the ventilator aims to adjust the pressure on a breath-to-breath basis to deliver the set normal volume. In Volume-Controlled ventilation, the doctor or nurse intermittently adjusts the set volume to deliver the normal volume of gas into the lungs. Both types of ventilation are used widely in neonatal units throughout the world and are considered safe. This study aims to find out whether one type of ventilation has any advantage over the other.

Who can participate?

Babies can take part in this study if they are born more than six weeks early and require ventilation for respiratory distress syndrome (breathing difficulties due to premature lungs). Only babies who are ventilated within the first 24 hours of life can be enrolled as this is when respiratory distress syndrome is likely to be at its worst.

What does the study involve?

Babies who are born more than six weeks early and who need ventilation within the first 24 hours of life in our unit, will be eligible for the trial if their parents agree to it. Because both types of ventilation are already in use in many neonatal units and are both considered standard treatments, we have had approval from the ethics committee and the trial sponsor to use a process of deferred consent to ask parents for permission for their babies to participate. This means that we randomly allocate each baby into one of the two groups before or just after ventilation is started. This is done by a random allocation process that has been prepared by an independent person who is not part of the trial. It will not interfere with any urgent treatment or procedures that a baby might need. There is a 50/50 chance that a baby will be allocated to either Volume Guarantee or to Volume-Controlled ventilation. We will then speak to the baby's parents to ask for permission for their baby to participate in the trial. If they agree, we will ask

them to sign a consent form. This means that we have permission to use anonymised information from the baby's medical records and ventilator for the purpose of the trial. If parents decline, we will not use information from the records for the study but their baby's ventilation will remain the same. This method of deferred consent means that we can gain information on both types of ventilation from the moment a baby is born whilst also allowing parents enough time to consider information about the trial and make a decision about whether they want their baby to participate. Each baby who participates in the trial will receive the allocated type of ventilation until the time that he/she no longer needs ventilation. If a baby needs to go back on a ventilator at any point, he/she will receive the same allocated type of ventilation. In all other aspects, all babies in the study will receive the high standard of care that is given to all babies in the neonatal unit.

What are the possible benefits and risks of participating?

Premature babies who require ventilation can encounter serious medical problems. These problems are mostly due to being born prematurely and sometimes due to being ventilated. However, babies who are on a ventilator would not survive without it so the benefits of ventilation outweigh the side effects. Side effects can include pneumothorax (air that leaks out of the lung into the space between the lungs and the ribs) and chronic lung disease (long term dependence on oxygen or breathing support). We do not expect any additional or new side effects related to Volume Guarantee or Volume-Controlled ventilation. Both are safe and used widely in neonatal units around the world. They have both been shown to reduce complications related to ventilation. We are not studying a new treatment, we are comparing two treatments that are already in use in units around the world to see if one is better than the other. Babies in the study will not undergo any extra blood tests or other tests compared to similar babies who are not in the study. We do not know if Volume Guarantee is better than Volume-Controlled ventilation, or vice versa. Some clinicians feel that Volume Guarantee may be better because it makes adjustments breath by breath but this has not been proven in a proper scientific manner. We cannot promise that this study will specifically help individual babies who take part but the information we get may provide more information about improving ventilation techniques in the future for premature babies with breathing difficulties.

Where is the study run from?

The study is running in the Neonatal Unit at The James Cook University Hospital, Middlesbrough, UK.

When is the study starting and how long is it expected to run for?

It started in July 2013. Initially we expected that it would take two years to enrol enough babies. However, it is likely to take about three years so the planned end date is June 2016. It will then take another 6-12 months to analyse the results.

Who is funding the study?

South Tees Hospitals NHS Foundation Trust (UK).

Who is the main contact?

Dr Helen Chitty

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Contact information

Type(s)

Scientific

Contact name

Dr Helen Chitty

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 7

Study information

Scientific Title

A randomised controlled trial comparing two methods of providing volume-targeted ventilation in preterm infants with respiratory distress syndrome: Volume Guarantee® versus Volume-Controlled ventilation

Acronym

The VoluVent Trial

Study objectives

The aim of this study is to compare the efficacy of two commonly used modalities of volume-targeted ventilation, Volume-Controlled ventilation and Volume Guarantee (delivered by AVEA® ventilators) using short-term clinically relevant outcomes, in infants born at <34 weeks gestation with respiratory distress syndrome. We hypothesize that infants assigned to Volume Guarantee will require 33% less time to achieve the predetermined 'success' criteria. As both modes of ventilation will be provided with the same machine, this should largely avoid any device-related bias.

On 09/09/2014 the anticipated end date was changed from 31/07/2015 to 30/06/2016.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Northeast York Ethics Committee approval obtained on 03/07/2013 with minor amendments approved on 19/07/2013 (ref: 13/NE/0182). A substantial amendment made to the protocol to include the use of deferred consent was given a favourable opinion by the ethics committee on 18/11/2013

Study design

Pragmatic single-centre unmasked randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled 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

Respiratory distress syndrome in preterm infants

Interventions

Volume Guarantee ventilation and Volume-Controlled ventilation

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The primary outcome measure is the duration (in hours) of mechanical ventilation via an endotracheal tube from study entry until achievement of the predetermined success criteria.

Success criteria include:

1. A mean airway pressure of <8cm H₂O and a fractional inspired oxygen concentration (FiO₂) ≤0.35 maintained for 6 consecutive hours, followed by
2. Successful completion of the spontaneous breathing test.

If there is an unplanned extubation after which the infant does not require reintubation, this will also be classed as success and results will be analysed on an intention to treat basis.

Secondary outcome measures

1. Total duration (in hours) of mechanical ventilation via an endotracheal tube until first extubation

2. Requirement for reintubation within 72 hours of extubation
3. Total duration (in hours) of mechanical ventilation via an endotracheal tube until successful extubation
4. Pulmonary air leak while receiving mechanical ventilation (including pneumothorax, pneumomediastinum, pneumopericardium, pneumatocele, and pulmonary interstitial emphysema)
5. Number of episodes of hypocarbia during mechanical ventilation (defined as carbon dioxide tension of less than 4.0 kPa) requiring adjustment of ventilation
6. Total duration (in hours) of non-invasive artificial respiratory support including nasal continuous positive airway pressure (CPAP), bilevel nasal CPAP and high flow nasal cannulae
7. Number of infants requiring rescue treatment (high frequency oscillatory ventilation)
8. Need for continuous or intermittent supplemental oxygen at a postmenstrual age of 28 days and 36 weeks corrected gestational age
9. Bronchopulmonary dysplasia requiring home oxygen therapy or continuation of any form of respiratory support at home

Mortality:

1. Death before discharge from hospital

Neurological outcomes:

1. Severe intraventricular haemorrhage (grades 3 or 4 according to the Papile classification)
2. Periventricular leukomalacia

Outcomes related to prematurity:

1. Retinopathy of prematurity requiring laser treatment
2. Patent ductus arteriosus requiring medical or surgical treatment
3. Necrotising enterocolitis (Bell stage 2 or greater)
4. Intestinal perforation not due to necrotising enterocolitis
5. Number of confirmed episodes of infection (positive cultures from blood and cerebrospinal fluid at a time when the infant showed clinical signs of infection)

Overall study start date

23/07/2013

Completion date

30/06/2016

Eligibility

Key inclusion criteria

Current inclusion criteria as of 09/09/2014:

1. < 34 weeks gestation at birth
2. <24 hours old at the time of initial intubation
3. Require intubation and mechanical ventilation for respiratory distress syndrome
4. Written informed consent obtained from parents within 36 hours of initial intubation

Previous inclusion criteria:

1. <34 weeks gestation at birth
2. <24 hours old at the time of initial intubation
3. Require intubation and mechanical ventilation for respiratory distress syndrome
4. Written informed consent obtained from parents within 12 hours of initial intubation

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

112 infants (the calculated sample size is 102 infants required to complete the trial, therefore we are aiming to enrol 112 to account for a 10% possible withdrawal rate)

Total final enrolment

113

Key exclusion criteria

1. Do not fulfill the inclusion criteria or,
2. Require mechanical ventilation for reasons other than respiratory distress syndrome or,
3. Have a known congenital anomaly likely to adversely affect the respiratory system or life expectancy.

Date of first enrolment

23/07/2013

Date of final enrolment

30/06/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The Neonatal Unit

Middlesbrough

United Kingdom

TS4 3BW

Sponsor information**Organisation**

South Tees Hospitals NHS Foundation Trust (UK)

Sponsor details

c/o Mr A Owens
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TS4 3BW

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02js17r36>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Neonatal Research Department and the Directorate of Neonatology, South Tees Hospitals NHS Foundation Trust (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

2017 results presented at the Neonatal Society 2017 Summer Meeting in <https://www.neonatalsociety.ac.uk/2017/06/30/comparing-two-types-of-volume-targeted-ventilation-in-preterm-infants-with-respiratory-distress-syndrome-the-voluvent-randomised-controlled-trial/> (added 26/10/2020)

2018 results in thesis <https://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.779830> (added 26/10/2020)

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No