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# Volume Guarantee or Volume-Controlled ventilation

**Submission date**
02/09/2013

**Recruitment status**
No longer recruiting

**Registration date**
09/12/2013

**Overall study status**
Completed

**Last Edited**
26/10/2020

**Condition category**
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 babys 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 babys 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 babys 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 babys 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 babys 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 $H_2O$ and a fractional inspired oxygen concentration ($FiO_2$) ≤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
Research and Development Department
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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 |