

A pilot study to compare high versus low tidal volume for mechanical ventilation in preterm babies with respiratory distress syndrome

Submission date 29/05/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/06/2020	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

Very premature babies (those of less than 32 weeks gestation or weighing less than 1500g) are born with lungs that have not yet fully developed. These babies may need help to breathe with the support of machines (mechanical ventilation) until their lungs are developed enough to do the work on their own. Traditionally, mechanical ventilation has been provided by controlling the pressure or volume of air delivered by these machines (ventilators). Recent studies have shown that controlling the volume works better than controlling pressure and has fewer side effects. The volume controlled ventilation works by controlling the amount of air/oxygen delivered at each breath (tidal volume). However, the tidal volume delivered by ventilators in clinical practice varies considerably, from 4-8ml/kg. This is important as, although lower tidal volumes can prevent the lungs from being damaged, they can also make the baby work harder at their breathing than they should. Some new advances in the technology means that there are now better ventilators that can deliver more accurate tidal volumes than before. We have therefore decided to take a closer look at what may be the best tidal volume to use in terms of performance and preventing side effects. Here, we are comparing the effects of the lower end of what is considered a normal tidal volume (4-5 ml/kg) to those of a higher normal tidal volume (7-8 ml/kg) delivered by mechanical ventilation to premature babies.

Who can participate?

Premature babies needing mechanical ventilation, weighing between 500-1500g or of no more than 32 weeks gestation at birth.

What does the study involve?

The babies are randomly allocated into one of two groups. Those in group 1 are given the lower normal tidal volume of air (4-5 ml/kg) via mechanical ventilation. Those in group 2 are given the higher normal tidal volume of air (7-8 ml/kg). We then compare the two groups to see which babies come off the ventilator first.

What are the possible benefits and risks of participating?

Not provided at registration.

Where is the study run from?
University Hospital of North Tees (UK)

When is the study starting and how long is it expected to run for?
July 2013 to February 2015

Who is funding the study?
North Tees and Hartlepool Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Prof Samir Gupta
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Contact information

Type(s)
Scientific

Contact name
Prof Samir Gupta

Contact details
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Additional identifiers

Integrated Research Application System (IRAS)
126072

Protocol serial number
IRAS Project ID: 126072

Study information

Scientific Title
HILO Trial - A comparative pilot study of High versus LOw tidal volume for mechanical ventilation in very low birth weight preterm babies with respiratory distress syndrome. A randomised controlled trial

Acronym
HILO Trial

Study objectives

The time to achieve a 25% reduction in peak pressure in very premature babies receiving mechanical breathing support using volume-targeted ventilation is less using high normal tidal volume (7-8 ml/kg) as compared to low normal tidal volume (4-5 ml/kg).

Null hypothesis: There is no difference in time to achieve 25% reduction in peak pressure using either 7-8 ml/kg or 4-5 ml/kg tidal volume.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sunderland Ethics Committee; ref. 13/NE/0110

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory distress syndrome

Interventions

The study would involve randomising the babies to low tidal volume (4-5 ml/kg) or high tidal volume (7-8 ml/kg) at birth using volume guarantee mode of ventilation. We would also collect tracheal aspirate before surfactant. The babies would then have a standard management on ventilation without altering the tidal volume.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The time to achieve 25% reduction in peak pressure

Key secondary outcome(s)

1. Duration of intubation
2. Incidence of pulmonary and non-pulmonary complications i.e., pneumothorax, bronchopulmonary dysplasia, intraventricular haemorrhage
3. Impact on inflammatory markers in tracheal aspirate
4. Survival to discharge

Completion date

28/02/2015

Eligibility

Key inclusion criteria

1. Preterm babies weighing 500-1500g or ≤ 32 weeks of gestation at birth
2. Requirement of intubation and mechanical ventilation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Serious underlying congenital anomaly
 - 1.1. Congenital diaphragmatic hernia
 - 1.2. Cyanotic congenital heart disease
 - 1.3. Airway anomalies
 - 1.4. Abdominal wall defects
2. Multiple pregnancies only the first-born were enrolled and randomized; the others received the same strategy but were not be enrolled
3. Babies initiated on ventilation after 12 hours of life or transferred from other centres

Date of first enrolment

18/07/2013

Date of final enrolment

28/02/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Consultant Neonatologist

Stockton on Tees

United Kingdom

TS19 8PE

Sponsor information

Organisation

North Tees and Hartlepool Hospitals NHS Trust (UK)

ROR

<https://ror.org/04zzrht05>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

North Tees and Hartlepool Hospitals NHS Foundation Trust (UK); ref.: CH-087

Results and Publications

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