ISRCTN86307399 https://doi.org/10.1186/ISRCTN86307399

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

Registration date
14/08/2014

Overall study status
Completed

Last Edited
25/06/2020

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
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 of 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

EudraCT/CTIS number

IRAS number
126072

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 measure

The time to achieve 25% reduction in peak pressure

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

Overall study start date
18/07/2013

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

Age group
Neonate

Sex
Both

Target number of participants
70

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
England

United Kingdom

Study participating centre
Consultant Neonatologist
Stockton on Tees
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TS19 8PE

Sponsor information

Organisation
North Tees and Hartlepool Hospitals NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

2019 thesis in http://etheses.dur.ac.uk/13320/ (added 25/06/2020)

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