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Pressure Support ventilation: Short term physiological effects in neonates during weaning from intermittent positive pressure ventilation (IPPV)

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
09/10/2014

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544139654

Study information

Scientific Title

Study objectives
To investigate if Pressure Support Ventilation (PSV) performs as well as conventional trigger ventilation modes synchronised intermittent mandatory ventilation (SIMV) and synchronised intermittent positive pressure ventilation (SIPPV), in supporting newborn infants receiving mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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

Health condition(s) or problem(s) studied
Neonatal Diseases: Ventilation

Interventions
Consent would be sought to participate in the study.

The patient would be eligible to commence the study when in a stable condition with an inspired oxygen concentration of less than or equal to 60% and a decision made by the treating clinician to commence weaning from the ventilator.

Patients on the neonatal unit at The Rosie maternity hospital are ventilated on the synchronised triggered ventilation modes of either synchronised intermittent mandatory ventilation (SIMV) or synchronised intermittent positive pressure ventilation (SIPPV). If the patient is on SIMV, their

mode of ventilation will be altered to SIPPV (provided the patient is receiving a supported respiratory rate of greater than 40 breaths per minute, this will be equivalent to SIMV). If the patient is originally ventilated on SIMV and hence changed to SIPPV, a 1 hour period will be allowed prior to commencing the study in order for the patient to settle.

Once the study begins each infant will be allocated randomly to a start mode, with half of the patients starting on SIPPV and the other half starting on pressure support ventilation (PSV).

PSV is a mode of ventilation which allows each patient breath to be both patient initiated and patient terminated, therefore the patient sets the duration of their own inspiratory time. Each patient breath is supported by the ventilator. In the conventional modes of ventilation, SIMV and SIPPV each breath is again supported and is patient initiated but is ventilator terminated, the patient receives a preset inspiratory time, set by the clinician.

The ventilator settings on changing from SIPPV to PSV will be left unchanged except the inspiratory time will be increased to 0.5 seconds during the PSV mode. This is a limit on the maximum inspiratory time and will allow for a sighing respiration. Changing a patient from SIPPV to PSV and vice versa only requires the pressing of a switch on the Dräger 8000 plus ventilator.

The patient will remain on the initial mode of ventilation for 60 minutes and will then change to the alternate mode of ventilation for another 60 minute period.

During the study the newborns will receive standard intensive care monitoring, this will include measures of their heart rate and blood pressure, in addition each infant will have continuous monitoring of their blood carbon dioxide and oxygen concentrations by a transcutaneous monitor. This is a small 0.5 cm diameter probe attached to the skin and is a standard piece of monitoring equipment in the intensive care setting. In addition to the physiological parameters mentioned, during the study the patients will be observed for their level of comfort. In a few cases to verify the reproducibility of our comfort scores a video of the newborns will be taken. They will be used solely for this purpose and will be destroyed following the study.

During the study, data will be collected directly from the ventilators to analyse subsequently for various ventilator dependent parameters.

After the 2 hour study period the patient will be continued on the ventilatory mode chosen by the clinician.

This study requires few additional procedures beyond the routine care carried out on the neonatal unit. A blood gas will be taken prior to commencing the study, but we will restrict the timing of our study to coincide with when this would be routinely required. Other 'procedures' additional to routine care would be the use of a transcutaneous monitor (if the infant did not have one already attached) and the collection of data from the Drager ventilator and patient monitor, both of which are completely non invasive.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/12/2003

Completion date
18/12/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
19/12/2003

Date of final enrolment
18/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box No 226
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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?

Results article	results	01/03/2007	Yes	No