

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	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/10/2014	Condition category Neonatal Diseases	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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 Dräger ventilator and patient monitor, both of which are completely non invasive.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

18/12/2006

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

Study participating centre

Box No 226

Cambridge

United Kingdom

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Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Cambridge Consortium - Addenbrooke's (UK)

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?
Results article	results	01/03/2007		Yes	No