

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/10/2014	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 Dräger 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**

Cambridge

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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?
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[Results article](#)

results

01/03/2007

Yes

No