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Pressure Support Ventilation (PSV) or Synchronised Intermittent Mandatory Ventilation (SIMV) for weaning preterm infants on mechanical ventilation

Submission date
23/02/2011

Recruitment status
No longer recruiting

Registration date
08/03/2011

Overall study status
Completed

Last Edited
20/11/2017

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
Most premature infants need breathing support through a tube in their wind pipe. We know providing artificial breathing support can lead to long-term problems with the growth of the lungs. Although most clinicians would agree when to start breathing support for a preterm infant, there is as yet no consensus on when to reduce this support, also called 'weaning on mechanical ventilation'. This study is investigating two different methods of 'weaning' breathing support in premature infants. Until recently, most units in the UK used synchronised intermittent mandatory ventilation (SIMV). SIMV matches a fixed number of breaths on the breathing support machine and over a period of time the fixed number of breaths is reduced before the breathing tube is taken out (extubation). However, advances in technology have led to newer modes of ventilation. One such mode is pressure support ventilation (PSV). In PSV the infant is in charge of all aspects of breathing. The medical team would only set the permissible pressure level to support the spontaneous breaths, so weaning on mechanical ventilation would only be to decrease the pressure support before the tube is taken out. In adults PSV is preferred as this is more comfortable.

Who can participate?
Preterm infants born between 23+0 weeks and 32 weeks gestation who were ventilated for at least 6 hours for Respiratory Distress Syndrome (RDS).

What does the study involve?
Participating infants are randomly allocated to one of the two modes of 'weaning' breathing support. It is usual for some infants to not tolerate the reduction in breathing support and 'fail'. If at any stage the infant does not tolerate any of the weaning methods then the medical team assess them as per usual policy. All other aspects of their care are provided as per unit policy and current practice.

What are the possible benefits and risks of participating?
At present there is no perceived benefit or risk of one method over the other. However, at the end of the study both the groups would be compared to find out if there is a difference.

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

When is the study starting and how long is it expected to run for?
January 2010 to May 2013

Who is funding the study?
University Hospital of North Tees (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
Version 13, 29/12/2010

Study information

Scientific Title
Pressure Support Ventilation (PSV) or Synchronised Intermittent Mandatory Ventilation (SIMV) for weaning preterm infants on mechanical ventilation: a multi-centre randomised controlled trial

Acronym
POST-UK Study

Study objectives
The trial is investigating the practicability of PSV as opposed to SIMV for weaning on mechanical ventilation in preterm infants needing mechanical ventilatory support for Respiratory Distress Syndrome (RDS).

The primary endpoint of the trial is defined as time from entry into the trial (predefined priori of mean airway pressure of less than 10cm, oxygen requirement of less than 40% and spontaneous breath rates of at least 50%) to the time when the infant is ready for extubation demonstrated by passing then minute ventilation test (MVT).

The null hypothesis for the trial would find no difference between the two modes. However any difference between the two modes would be calculated using appropriate statistical calculations.

The study is planned across two tertiary care units in the North East of England.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside Research Ethics Committee, 10/01/2011

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory distress syndrome in preterm babies

Interventions

The intervention arm would receive pressure supported mechanical breaths for all the spontaneous breaths generated by the infant and the control arm would receive SIMV mode of respiratory support as is currently practiced.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The primary endpoint is duration of weaning on mechanical ventilation - defined as time from commencing weaning in the assigned mode of respiratory support to the time when the infant is ready for extuabtion demonstrated by passing the MVT

Key secondary outcome(s))
1. Total duration of mechanical support through the endotracheal (ET) tube
2. Total duration of respiratory support including non invasive respiratory support
3. Discharge on home oxygen
4. Complications of prematurity

Completion date
26/01/2013

Eligibility

Key inclusion criteria
1. Preterm infants with RDS, stratified into three groups (23+0 to 25+6, 26+0 to 28+6 and 29+0 to 31+6 weeks) based on their gestation at birth would be enrolled if they are needing mechanical ventilation through an endotracheal tube for at least 6 hours
2. Signed parental consent is obtained before randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Severe congenital malformation
2. Neuromuscular disorder demonstrated clinically with decreased muscular tone
3. Upper airway anomaly
4. Infants transferred from other unit who have met the study entry criteria on admission to the neonatal unit

Date of first enrolment
26/01/2011

Date of final enrolment
26/01/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital of North Tees
Stockton
United Kingdom
TS19 8PE

Sponsor information

Organisation
North Tees and Hartlepool NHS Foundation Trust (UK)

ROR
https://ror.org/04zzrht05

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of North Tees (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes