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Pressure Support Ventilation (PSV) for ventilation of newborn infants

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/05/2017	Neonatal Diseases	[ ] Record updated in last year

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
N0436130508

Study information

Scientific Title
Pressure Support Ventilation (PSV) for ventilation of newborn infants

Study objectives
To investigate if PSV performs as well as conventional trigger ventilation modes (SIPPV, SIMV) 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
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
1. Synchronised intermittent positive pressure ventilation (SIPPV)
2. Synchronised intermittent mandatory ventilation (SIMV)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
A change in mean airway pressure.

Secondary outcome measures
Oxygenation index (OI), comfort score, tidal volumes, PaCO2, degree of asynchrony during exhalation.

Overall study start date
30/04/2003

Completion date
30/06/2008

Eligibility

Key inclusion criteria
Newborn infants in the convalescent phase of respiratory distress syndrome and being weaned from mechanical ventilation

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
30/04/2003

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Neonatal Unit
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (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