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Optimising arterial carbon dioxide during initial stabilisation in ventilated newborn infants: a randomised controlled trial

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

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

Protocol serial number
N0544093462

Study information

Scientific Title

Study objectives
Optimising carbon dioxide in ventilated newborn infants.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neonatal Diseases: Artificial ventilation

Interventions
1. Synchronised Intermittent Postive Pressure Ventilation (SIPPV)
2. SIPPV plus Volume Guarantee

Infants requiring artificial ventilation will be entered in the trial following antenatal parental assent. Formal consent will be obtained within 24 h of birth. Study infants will be randomly assigned to either receive Synchronised Intermittent Positive Pressure Ventilation (SIPPV) or SIPPV plus Volume Guarantee (VG). The assigned mode of ventilation will continue until arterial access has been obtained and results of blood gas analysis are available. The infants will then continue on the clinician determined mode of ventilation.

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
30/04/2003

Eligibility

Key inclusion criteria
40 infants showing a 50% difference in the incidence of out of range in the first hour of life

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
01/06/2000

Date of final enrolment
30/04/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Box No 226
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's Hospital NHS Foundation Trust (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