

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	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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