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Continuous positive airway pressure (CPAP) or Synchronised intermittent positive airway pressure (SiPAP™) study

Submission date	Recruitment status	[X] Prospectively registered
30/01/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/02/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/06/2016	Pregnancy and Childbirth	[ ] 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
N/A

Study information

Scientific Title
Randomised controlled trial of synchronised intermittent positive airway pressure (SiPAP™) versus continuous positive airway pressure (CPAP) as a primary mode of respiratory support in preterm infants with respiratory distress syndrome (RDS)

Acronym
CoSi Study

Study objectives
The purpose of this study is to compare synchronised intermittent positive airway pressure (SiPAP™) with continuous positive airway pressure (CPAP) as a primary mode of non-invasive respiratory support, in premature newborn infants with respiratory distress syndrome (RDS). We hypothesise that the use of SiPAP™ will result in a reduction in the rates of endotracheal intubation and mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
County Durham and Tees Valley 1 REC, 11/02/2009, ref: 09/H0905/4
Amendments approved: 23/02/2009

Study design
Randomised controlled multi-centre unblinded pilot 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
Respiratory distress syndrome

Interventions
Two modes of non-invasive ventilation:
1. Continuous positive airway pressure - active control
2. Synchronised intermittent positive airway pressure (SiPAP™) - intervention

Treatment will be until non-invasive respiratory support has been discontinued and the baby has remained stable off non-invasive support for more than 7 days or where the baby has failed on non-invasive respiratory support and been intubated and mechanically ventilated. Follow-up will be until the time of final discharge home but not beyond.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Failure of non-invasive ventilation necessitating intubation and mechanical ventilation (placement of a tube in the windpipe and full artificial breathing support via machine) in the first 72 hours of treatment with either CPAP or SiPAP™. This outcome is binary categoric as babies will be either 'intubated and mechanically ventilated' or not; providing a proportion of infants in each treatment arm who meet this outcome.

Secondary outcome measures
Assessed from the medical notes and nursing charts at discharge they all constitute usual care of preterm infants at these gestations, who are intensive care level patients and continuously monitored whilst receiving respiratory support. It is impossible to specify an exact timepoint for many of the outcomes as they can occur at any time for these infants, hence an assessment of the occurrence or not of the outcome on discharge by reviewing the case notes.

1. Death prior to discharge - at time of death
2. RDS severity grading - at randomisation
3. Reason for failure of non-invasive ventilation -at failure
4. Timing of failure of non-invasive ventilation - at failure
5. Total duration of any form of respiratory support - at discharge - review of notes
6. Duration of invasive mechanical ventilation - at discharge - review of notes
7. Duration of supplemental oxygen - at discharge - review of notes
8. Bronchopulmonary dysplasia (diagnosis) - at 36 weeks gestation
9. Pneumothorax (diagnosis) - at discharge - review of notes
10. Postnatal steroid use - at discharge - review of notes
11. Necrotising enterocolitis diagnosis - at discharge - review of notes
12. Necrotising enterocolitis needing surgery - at discharge - review of notes
13. Gastric distension - assessed clinically 6-8 hourly whilst on non-invasive ventilation, outcome assessed at discharge - review of notes
14. Sepsis diagnosis - at discharge - review of notes
15. Nasal injuries - assessed clinically 6 - 8 hourly whilst on non-invasive ventilation, outcome assessed at discharge - review of notes
16. Nasal injuries - grading and treatment required, at discharge - review of notes
17. Retinopathy of prematurity - greater than grading and treatment (surgery), at discharge - review of notes
18. Patent ductus arteriosus - greater than treatment required, at discharge - review of notes
19. Abnormal cranial ultrasound scan - report worst scan for grading, at discharge - review of notes
20. Cranial abnormalities periventricular leukomalacia (PVL) or intraventricular haemorrhage (IVH) - at discharge - review of notes
21. Time to full enteral feeds - in days to reach 150 ml/kg/day, at discharge - review of notes

22. Change in weight from birth to 36 weeks postmenstrual age - Z scores, at discharge - review of notes
23. Change in weight from birth to discharge - Z scores at discharge - review of notes
24. Length of hospital stay - at discharge - review of notes
25. Duration of intensive and high dependency care - at discharge - review of notes

Overall study start date
02/03/2009

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Gestational age - 28+0 to 31+6 weeks by scan estimated date of delivery (EDD) inclusive
2. Signs of respiratory distress requiring non-invasive respiratory support
3. Inborn
4. Signed written parental consent for participation
5. Randomised by 6 hours of age or less

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Total recruitment = 130 preterm infants

Key exclusion criteria
1. Gestational age - less than 27+6 weeks or greater than 32+0 weeks
2. Endotracheal intubation and ventilation at any time prior to enrolment
3. Respiratory distress meeting failure criteria of non-invasive ventilation and requiring intubation and mechanical ventilation
4. Congenital or neuromuscular disorders diagnosed antenatally or at the time of birth, known to interfere with respiratory function or ability to breathe; including significant abnormalities of the upper airway
5. Refusal of signed written parental consent

Date of first enrolment
02/03/2009

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Directorate of Neonatology
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Trust (UK)

Sponsor details
James Cook University Hospital
Marton Road
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England
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Sponsor type
Hospital/treatment centre

Website
http://www.southtees.nhs.uk/live/

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (UK) - Directorate of Neonatology

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