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Measurements of work of breathing in newborn during respiratory support

Submission date	Recruitment status	[ ] Prospectively registered
26/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2010	Respiratory	[ ] 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
09.03.2008 / V1; AL002a

Study information

Scientific Title
Assessment and Measurement of Work of Breathing and Dynamic Lung Mechanics in Non-Invasive Respiratory Support: A prospective randomised controlled trial

Acronym
nCPAP

Study objectives
Study rationale:
This is the first study investigating changes in respiratory muscle work load of rib cage muscles, diaphragm and abdominal muscles at different levels of neonatal Continuous Positive Airway Pressure (nCPAP) in neonates and correlating those invasive measurements of work of breathing with respiratory parameters derived by non-invasive techniques.

Optimising work of breathing might improve ventilation strategies by avoiding respiratory muscle fatigue and respiratory muscle disuse atrophy. Additionally it might reduce energy expenditure, promoting weight gain and general development of the preterm infant and reduce the need for mechanical ventilation leading to a reduction in nosocomial infection, patient morbidity, hospital stay and cost.

Hypotheses:
Null Hypotheses
Respiratory muscle work load as measured by the pressure time product is not affected by changes in the level of nasal continuous positive airway pressure and does not correlate with changes in clinical parameters (respiratory rate, fraction of inspired oxygen and heart rate) and parameters derived by Respiratory Inductance Plethysmography (phase angle, abdominal excursion and expiratory time).

Alternative Hypotheses:
1. Respiratory muscle work load as measured by pressure time product is affected by changes in the level of nasal continuous positive airway pressure.
2. Changes in phase angle and expiratory time derived by non-invasive Respiratory Inductance Plethysmography correlate with changes in pressure time product derived by oesophageal gastric pressure transducer at different levels of nasal continuous positive airway pressure.
3. Reduction of pressure time product correlates with improvement of clinical parameters (heart rate, respiratory rate, fraction of inspired oxygen and peripheral oxygen saturation).

Aim and objectives:
The overall aim of the study was to investigate if work of breathing as measured by invasive techniques can be predicted by respiratory parameters derived by non-invasive techniques.

The objectives were:
1. To develop a monitoring system for the measurement of work of breathing in neonates on nCPAP.
2. To validate the new monitoring system.
3. To measure changes in pressure time products at different levels of nCPAP.
4. To determine the correlation between pressure time product derived by oesophageal gastric pressure transducer and phase angle and expiratory time derived by respiratory inductance plethysmography at different levels of nCPAP.

5. To determine whether there is a correlation between pressure time product and clinical parameter including respiratory rate, fraction of inspired oxygen, peripheral oxygen saturation and heart rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Research and Ethics Committee University of Stellenbosch, Parow, South Africa approved on the 7th of May 2008 (ref: N08/03/088)

Study design
Randomised prospective clinical 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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Respiratory Failure

Interventions
Each participant received nCPAP at pressure levels of 2, 4, 6 and 8 cm H2O. The sequence of the pressure levels for each subject was randomised to avoid a 'volume history effect' (an increase of lung volume with increased CPAP).

Lung function parameters were continuously measured at each CPAP level via Respiratory Inductance Plethysmography and Oesophageal Gastric Pressure Transducer. Measured parameters were oesophageal pressure, gastric pressure, phase angle, abdominal excursion, expiratory time, respiratory rate, fraction of inspired oxygen and heart rate.

The total duration of intervention is one hour, the participants are all on an intensive care or special care neonatal unit, therefore nurses and doctors will continuously record vital signs until the participant is discharged from the unit. The principal investigator is also the neonatal consultant on those wards and will be informed at any time if participants deteriorate shortly after the study (within 24 hours). Long term follow up is not planned.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pressure time product
All outcome variables will be measured 10 -15 minutes after each change of nCPAP level for a period of 5 minutes

Secondary outcome measures
1. Phase angle
2. Abdominal excursion
3. Respiratory rate
4. Expiratory time
5. FiO2
All outcome variables will be measured 10 -15 minutes after each change of nCPAP level for a period of 5 minutes

Overall study start date
01/06/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Neonates requiring nCPAP
2. Weight less equal than 500g

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Parents refusing consent
2. Fraction of Inspired Oxygen (FiO2) > 0.5cc
3. Pneumothorax
4. Necrotizing Enterocolitis
5. Haemodynamically unstable

6. Imminent intubation
7. Weaning off CPAP
8. Major congenital malformation

Date of first enrolment
01/06/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
England

South Africa

United Kingdom

Study participating centre
Imperial College
London
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Sponsor information

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Sponsor type
Industry

ROR
https://ror.org/05bk57929

Funder(s)

Funder type
Charity

Funder Name
Save the Baby Charitable Trust (UK)

Funder Name
Sydney and Phyllis Goldberg Charitable 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