# Measurements of work of breathing in newborn during respiratory support

| Submission date   | Recruitment status   | <ul> <li>Prospectively registered</li> </ul>  |
|-------------------|----------------------|---|
| 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          | <ul><li>Record updated in last year</li></ul> |

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Andrea Lomp

#### Contact details

Imperial College Department of Paediatrics Norfolk Place London United Kingdom W21PG

# Additional identifiers

Protocol serial number 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**

## **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

# Study type(s)

Treatment

# 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(s)

Pressure time product

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

# Key secondary outcome(s))

- 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

# Completion date

01/12/2010

# Eligibility

## Key inclusion criteria

- 1. Neonates requiring nCPAP
- 2. Weight less equal than 500g

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

# Age group

Neonate

#### Sex

All

#### 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

**United Kingdom** 

England

South Africa

# Study participating centre

# Imperial College

London United Kingdom W21PG

# Sponsor information

## Organisation

University of Stellenbosch (South Africa)

#### **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**

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?

Participant information sheet Participant informatio

Participant information sheet 11/11/2025 11/11/2025 No