

# Physiologic measurements using continuous neonatal blood gas monitoring in preterm infants requiring mechanical ventilation for respiratory failure

|                                        |                                                |                                                      |
|----------------------------------------|------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>29/09/2006   | <b>Recruitment status</b><br>Stopped           | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>29/09/2006 | <b>Overall study status</b><br>Stopped         | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>27/01/2014       | <b>Condition category</b><br>Neonatal Diseases | <input type="checkbox"/> Individual participant data |
|                                        |                                                | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N0227165397

## Study information

## Scientific Title

### Study objectives

Variability in arterial PsO<sub>2</sub> and PaCO<sub>2</sub> as measured continuously by multiparameter arterial sensor (NeotrendR) in babies on different modes of mechanical ventilation.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Primary study design

Interventional

### Study design

Single centre randomised crossover clinical trial

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Neonatal Diseases

### Interventions

Single-centre randomised crossover clinical trial.

Updated 27/01/2014: This trial was stopped because the manufacturers of the Neotrend /Paratrend device used for continuous blood gas monitoring went out of business and the product was no longer available.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome(s)

Coefficient of variation in blood gases (PaO<sub>2</sub> and PaCO<sub>2</sub>) while receiving mechanical ventilation.

### Key secondary outcome(s)

Incidental physiological data that are routinely collected in babies requiring intensive care, such as core temperature, arterial PH.

### Completion date

31/12/2006

### Reason abandoned (if study stopped)

Lack of staff/facilities/resources

# Eligibility

## Key inclusion criteria

Preterm newborn infants < 34 weeks gestation, requiring mechanical ventilation for respiratory failure.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Neonate

## Sex

Not Specified

## Key exclusion criteria

All babies not receiving mechanical ventilation for respiratory failure.

## Date of first enrolment

01/06/2005

## Date of final enrolment

31/12/2006

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

South Tees Hospital Trust

Middlesbrough

United Kingdom

TS4 3BW

# Sponsor information

## Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

# Funder(s)

## Funder type

Government

## Funder Name

South Tees Hospitals NHS Trust

## Funder Name

The James Cook University Hospital

## Funder Name

NHS R&D Support Funding

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration