

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

Submission date 29/09/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/01/2014	Condition category 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

Dr M K Lal

Contact details

South Tees Hospital Trust
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
+44 (0)1642 282724
Mithilesh.lal@stees.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0227165397

Study information

Scientific Title

Study objectives

Variability in arterial PsO₂ and PaCO₂ 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

Study design

Single centre randomised crossover clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Coefficient of variation in blood gases (PaO₂ and PaCO₂) while receiving mechanical ventilation.

Secondary outcome measures

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

Overall study start date

01/06/2005

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

Age group

Neonate

Sex

Not Specified

Target number of participants

10

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

England

United Kingdom

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

South Tees Hospitals NHS Trust

Funder Name

The James Cook University Hospital

Funder Name

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