

# Automated adjustment of inspired oxygen in premature infants requiring mechanical ventilation

<b>Submission date</b> 18/03/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/09/2016	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Oxygen therapy is common in newborn babies requiring intensive care. Whilst having too little oxygen can increase the risk of death or disability, too much oxygen can cause injury to the eyes, lungs and brain. Hence it is important to maintain oxygen levels in blood (saturation) within a target range. Studies show that it is possible to maintain saturation levels within the target range for about 50% of the time through manual adjustment of oxygen at the bedside. It is now possible to use an automated device to manage this. Its safety, feasibility and effectiveness is proven. We wish to investigate its relative effectiveness in the newborn population.

### Who can participate?

Preterm infants receiving mechanical ventilation requiring supplemental oxygen therapy.

### What does the study involve?

Over a 24-hour period each baby will have their oxygen levels maintained with manual adjustment for 12 hours and automated adjustment for 12 hours. The duration of time that the babies' oxygen saturation remains within the target range will be compared in the two periods.

### What are the possible benefits and risks of participating?

All treatment and care of such babies will remain exactly the same as is our standard.

### Where is the study run from?

Neonatal Intensive Care Unit, The James Cook University Hospital (UK).

### When is the study starting and how long is it expected to run for?

From September 2011 to August 2013.

### Who is funding the study?

Investigator initiated and funded (UK).

Who is the main contact?

Dr Mithilesh Lal

## Contact information

### Type(s)

Public

### Contact name

Dr Mithilesh Lal

### ORCID ID

<http://orcid.org/0000-0002-9156-229X>

### Contact details

The James Cook University Hospital  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

Version 3.0 / 19 September 2011

## Study information

### Scientific Title

Efficacy of automated control of inspired oxygen in ventilated preterm infants: a randomized control trial

### Acronym

CLIO-RCT

### Study objectives

The objective of this study is to evaluate the efficacy of the automatic FiO<sub>2</sub> control function in comparison to manual FiO<sub>2</sub> control during routine care in maintaining target range of SpO<sub>2</sub> between 90 to 95% using a randomized crossover design in ventilated preterm infants requiring supplemental oxygen therapy.

We hypothesized that there would be no difference between the automated and manual control periods in the primary outcome variable defined as the proportion of time with SpO<sub>2</sub> within the assigned target range of 90-95% plus time with SpO<sub>2</sub> above the assigned target range in room

air.

The safety null hypothesis of this study was that there would be no difference between automated and manual control periods in the proportion of time in severe hypoxemia defined as  $SpO_2 < 80\%$  and severe hyperoxemia defined as  $SpO_2 \geq 98\%$ , when not in room air.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

National Research Ethics Service (NRES) Committee North East - County Durham & Tees Valley UK, 23/11/2011, ref: 11/NE/0302

### **Study design**

Single-centre physiological crossover study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised cross over 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 failure in preterm infants requiring mechanical ventilation

### **Interventions**

This randomized crossover trial involved preterm infants who are mechanically ventilated and receiving supplemental oxygen. Each infant was studied for two consecutive 12-hour periods, one with inspired oxygen ( $FiO_2$ ) adjustment by the clinical team (manual) and the other by an automated device (CLIO) (automated), assigned in a random sequence.

### **Intervention Type**

Device

### **Primary outcome measure**

Proportion of time with pulse oximetry ( $SpO_2$ ) within the assigned target range of 90-95% during two consecutive 12-hour periods of automated and manual adjustment of inspired oxygen ( $FiO_2$ ).

### **Secondary outcome measures**

Proportion of time with pulse oximetry (SpO<sub>2</sub>) outside of the assigned target range of 90-95%, extreme hypoxemia (<80%) and hyperoxemia (≥98%) during two consecutive 12-hour periods of automated and manual adjustment of inspired oxygen (FiO<sub>2</sub>).

**Overall study start date**

19/09/2011

**Completion date**

31/08/2013

## Eligibility

**Key inclusion criteria**

Preterm infants were enrolled in the study if they met all of the following inclusion criteria:

1. Written informed parental consent
2. Receiving mechanical ventilation through an endotracheal tube
3. On supplemental oxygen at the time of enrolment and during the previous 24 hours
4. Without major congenital anomalies

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Major congenital anomalies
2. Not requiring supplemental oxygen during the previous 24 hours prior to enrollment.

**Date of first enrolment**

30/01/2012

**Date of final enrolment**

31/08/2013

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Neonatal Intensive Care Unit, The James Cook University Hospital**  
Marton Road  
Middlesbrough  
United Kingdom  
TS7 0LT

## **Sponsor information**

**Organisation**  
South Tees Hospital NHS Trust

**Sponsor details**  
Marton Road  
Middlesbrough  
England  
United Kingdom  
TS4 3BW

**Sponsor type**  
Hospital/treatment centre

**Website**  
[www.southtees.nhs.uk](http://www.southtees.nhs.uk)

**ROR**  
<https://ror.org/02js17r36>

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## **Results and Publications**

**Publication and dissemination plan**  
To be confirmed at a later date

**Intention to publish date**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2015		Yes	No