ISRCTN94119947 https://doi.org/10.1186/ISRCTN94119947

Automated adjustment of inspired oxygen in premature infants requiring mechanical ventilation

Submission date	Recruitment status	[_] Prospectively registered
18/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/09/2016	Neonatal Diseases	

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
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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 FiO2 control function in comparison to manual FiO2 control during routine care in maintaining target range of SpO2 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 SpO2 within the assigned target range of 90-95% plus time with SpO2 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 SpO2 < 80% and severe hyperoxemia defined as SpO2 ≥ 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 (FiO2) 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 (SpO2) within the assigned target range of 90-95% during two consecutive 12-hour periods of automated and manual adjustment of inspired oxygen (FiO2).

Secondary outcome measures

Proportion of time with pulse oximetry (SpO2) 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 (FiO2).

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

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?
Results article	results	01/11/2015		Yes	No