ISRCTN49239883 https://doi.org/10.1186/ISRCTN49239883

Randomized evaluation of two SpO2 alarm strategies during ventilation with automated oxygen supply control in the NICU

Submission date
15/02/2018

Recruitment status
No longer recruiting

Registration date
15/05/2018

Overall study status
Completed

Last Edited
08/05/2019

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
When infants in the neonatal intensive care unit require ventilation and oxygen supplementation, their oxygen levels are monitored by pulse oximetry (SpO2). In most Polish units, SpO2 alarms are set tightly with a relatively short alarm delay. This approach ensures that nurses are alerted to the possible need for an adjustment or other action. Centers setting their alarms loosely experience less frequent persistent alarms. This approach seems to be good as it reduces the number of false alarms and thus alarm fatigue. The aim of this study is to find out whether a loose alarm strategy reduces SpO2 alarm frequency without increasing over reliance on automation and increasing exposure to SpO2 extremes.

Who can participate?
Infants with respiratory (breathing) failure who are being ventilated and are in need of oxygen

What does the study involve?
Two oxygenation alarm strategies are used. The tight strategy sets the SpO2 alarms to trigger just outside the target range with a 30-second delay. The loose strategy sets the threshold wider with a 90-second delay. Infants are switched between the two strategies every 24 hours until the infant is stabilized and is placed on Infant Flow or for a total of up to 6 days, whichever is first. The relative frequency and duration of audible alarms are collected with a datalogger plugged in to the ventilator throughout the study.

What are the possible benefits and risks of participating?
The loose strategy may reduce the risk associated with alarm fatigue and make it easier to keep the infant in the target oxygenation range.

Where is the study run from?
Neonatology, Center of Medical Postgraduate Education (Poland)

When is the study starting and how long is it expected to run for?
October 2015 to July 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Małgorzata Warakomska

Contact information

Type(s)
Scientific

Contact name
Mrs Malgorzata Warakomska

Contact details
Broniewskiego 8a/2
Warsaw
Poland
01-785

Additional identifiers

Protocol serial number
A5

Study information

Scientific Title
Randomized evaluation of two SpO2 alarm strategies during automated FiO2 control in the NICU

Study objectives
The paradigm of setting SpO2 alarms during automated control ought to be different than during periods of manual control. In most Polish units, SpO2 alarms are set tightly with a relatively short alarm delay. This approach is typical during manual control to insure the nurses are alerted to the possible need for an FiO2 adjustment or other action. We currently use the same strategy when using CLiO2, as do many other centers. Our recent review of the Polish CLiO2 Use Registry determined that those centers setting their alarms loosely experienced less “frequent persistent” alarms. This approach seems to be good as it reduces the number of false alarms and thus alarm fatigue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Centre of Postgraduate Medical Education, 14/10/2015, ref: 77/PB/2015

Study design
Observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Newborn babies with respiratory failure ventilated in NICU with AVEA CLiO2 ventilator

Interventions
The study will compare two oxygenation alarm strategies, starting on the first day of life and ending with a transition in respiratory support or at 6 days, whichever occurred first. The tight strategy (TAS) set the SpO2 alarms to trigger just outside the target range, with a 30-second delay. The loose strategy (LAS) set the threshold wider with a 90-second delay.
The SpO2 target range setting on the A-FiO2 system was selected by the attending physician, with a nominal range of 88-95%. The study will enroll 20 subjects who need for oxygen and will cross over between these strategies every 24 hours until the infant is stabilized and is placed on Infant Flow or for a total of up to 6 days, whichever is first. The initial and daily changes to alarm settings were implemented by the research team.

Intervention Type
Device

Primary outcome(s)
The relative frequency and duration of audible alarms, collected with a datalogger plugged in to the ventilator throughout the study

Key secondary outcome(s))
The prevalence of SpO2 associated with hyperoxemia and hypoxemia, collected with a datalogger plugged in to the ventilator throughout the study

Completion date
15/07/2017

Eligibility

Key inclusion criteria
Infants with respiratory failure ventilated and with need of oxygen

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
26

Key exclusion criteria
1. 6 days of intervention
2. Clinical exacerbation
3. Weaned from AVEA-CLiO
4. Withdrawn consent

Date of first enrolment
27/06/2016

Date of final enrolment
15/07/2017

Locations

Countries of recruitment
Poland

Study participating centre
Neonatology, Center of Medical Postgraduate Education
Czerniakowska 231
Warsaw
Poland
00-416

Sponsor information

Organisation
Neonatology, Independent Public Clinical Hospital of Prof W. Orlowski

ROR
https://ror.org/059151f39

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/05/2019	08/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes