

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/05/2019	Condition category Neonatal Diseases	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design

Observational study

Primary study design

Observational

Secondary study design**Study setting(s)**

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

The prevalence of SpO2 associated with hyperoxemia and hypoxemia, collected with a datalogger plugged in to the ventilator throughout the study

Overall study start date

14/10/2015

Completion date

15/07/2017

Eligibility

Key inclusion criteria

Infants with respiratory failure ventilated and with need of oxygen

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

20

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

Sponsor details

Czerniakowska 231

Warsaw

Poland

00-416

Sponsor type

University/education

ROR

<https://ror.org/059151f39>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

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