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The feasibility and safety of the use of automated oxygen in babies admitted to the neonatal intensive care unit

Submission date
18/10/2021

Recruitment status
No longer recruiting

Registration date
28/10/2021

Overall study status
Completed

Last Edited
09/12/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
As both excess and shortage of oxygen can be harmful to a baby born prematurely (before the usual end of pregnancy) we investigate whether it is possible to use automated oxygen control and if this is better than manual control of oxygen by a nurse or other healthcare provider.

Who can participate?
Preterm babies admitted to one of the participating Neonatal Intensive Care Units (NICU), requiring respiratory support and extra oxygen can participate.

What does the study involve?
The study involves a control period of 8 hours on manual control of oxygen, followed by a study period where automated oxygen control is turned on but still supervised by the nurse that takes care of the baby. After this period another control period of 8 hours on manual control follows. During the study period, the baby's oxygen levels are continuously monitored.

What are the possible benefits and risks of participating?
Due to the short study period and the continuous monitoring why expect no benefits or harm for the baby.

Where is the study run from?
Erasmus MC/Sophia's Children's Hospital (The Netherlands)

When is the study starting and how long is it expected to run for?
August 2016 to January 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
K.P. Dijkman, k.dijkman@mmc.nl

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL51887.000.16

Study information

Scientific Title
Safety and feasibility of Predictive Intelligent Control of Oxygenation (PRICO) on the Neonatal Intensive Care Unit (NICU)

Study objectives
Fully automated FiO2 control conducted by this algorithm will keep SpO2 within a predefined target range more time and with less deviation than during routine standard clinical care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/08/2016, CCMO: Central Committee on Research Involving Human Subjects (Mailbox 16302, 2500BH The Hague, The Netherlands; +31 70 340 67 00; ccmo@ccmo.nl), ref: NL51887.000.16

Study design

Multicenter inteventional crossover feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preterm newborns with oxygen requirement

Interventions
Newborns on respiratory support requiring oxygen wil be subjected to an 8 hour study period of automated control of oxygen with the PRICO algorithm that is used to control O2 on the Fabian HFO ventilator (Acutronic Meical GmbH, Hirzel, Switzerland). The 8 hour study period is flanked by two 8 hour periods of routine manual control of oxygen which is the current stand of care.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Respiratory support

Primary outcome(s)
Time spent within the SpO2 target range measured using a pulse oximeter and logged at 1/s interval both during the study and during the control periods

Key secondary outcome(s))
Time spent below target range, time spent above target range, average FiO2 and SpO2 measured using a pulse oximeter and logged at 1/s interval both during the study and during the control periods

Completion date
01/01/2020

Eligibility

Key inclusion criteria
Newborns receiving respiratory support and a FiO2 moor than 21% while having an FiO2 of 95% or less and no plans to chnage ventilation mode during the next 24 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Major congenital of chromosomal defects
2. Plans to transfer the patient out within 24 hours
3. Plans to change ventilation mode within 24 hours

Date of first enrolment
27/09/2016

Date of final enrolment
27/12/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC/Sophia's Childrens Hospital
Wytemaweg 80
Rotterdam
Netherlands
3015CN

Study participating centre
Maxima Medical Center
De Run 4600
Veldhoven
Netherlands
5504DB

Sponsor information

Organisation
Erasmus MC - Sophia Children’s Hospital

ROR
https://ror.org/047afsm11

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Primary data	08/12/2022	09/12/2022	Yes	No
Participant information sheet			28/10/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		01/10/2015	28/10/2021	No	No