

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/10/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/12/2022	Condition category Respiratory	<input type="checkbox"/> 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

Contact name

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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 interventional 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 will 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 more than 21% while having an FiO₂ of 95% or less and no plans to change 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
Protocol file		01/10/2015	28/10/2021	No	No