Multicenter study of the performance of Fabian-PRICO for saturation targeting routine use in the NICU

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Investigate whether, in a routine clinical environment across a number of centers, the fabian-PRICO can adequately maintain oxygen saturation, with minimal staff intervention.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON50564

Source
ToetsingOnline

Brief title
PRICO performance in the NICU

Condition

- Neonatal respiratory disorders

Synonym
apnea of prematurity, Intermittent hypoxic events

Research involving
Human

Sponsors and support

Primary sponsor: Vyaire Medical
Source(s) of monetary or material Support: Vyaire Medical

Intervention

Keyword: closed-loop oxygen titration, PRICO

Outcome measures

Primary outcome

TARGET RANGE COMPLIANCE: Percent-Time with SpO2 between 90-95% or above 90% when FiO2= 21%

AVOIDANCE OF SpO2 EXTREMES: Percent-Time with SpO2 a) <80% and b) with >98% SpO2 with FiO2>21%.

Secondary outcome

The following data will be gathered as secondary study parameters: Demographics (gender, gestational age, weight and height etc.), median SpO2 and FiO2, manual adjustment of FiO2 and cinical exacerbations. The last item will consist of a short survey for nurses and/or physicians to ask them about their impressions/opinion on the use of fabian-PRICO, which is added to the study CRF.

Study description

Background summary

During their stay in the neonatal intensive care unit (NICU) nearly all infants require supplemental oxygen and some form of respiratory support. The supplemental oxygen ranges between 100% and mostly room air (i.e., requiring brief low levels of supplemental oxygen administration to address short apneic spells). The fraction of inspired oxygen (FiO2) is usually titrated manually on the basis of the peripheral oxygen saturation (SpO2) measured with pulse oximetry. In addition to targeting normoxemia, avoiding both hypoxemia and hyperoxemia are important goals during oxygen supplementation as these conditions are associated respectively with an increased risk of mortality and with morbidities including retinopathy of prematurity (ROP) and

bronchopulmonary dysplasia (BPD) [2], [3]. However, SpO2 control during routine care by manually adjusting the FiO2 is a challenging task that is often not successful. In fact, infants receiving supplemental oxygen spend approximately 50% of the time within, 30% of the time above, and 20% of the time below the intended SpO2 range [4], [5]. With the purpose of improving oxygen targeting, a Closed-Loop FiO2-SpO2 controller was developed for adjustment of FiO2 in response to changes in SpO2 and has been incorporated into the fabian ventilators. In this study this closed-loop algorithm (PRICO) is investigated in routine clinical use.

Study objective

Investigate whether, in a routine clinical environment across a number of centers, the fabian-PRICO can adequately maintain oxygen saturation, with minimal staff intervention.

Study design

Randomized, cross-over study

Intervention

This study will compare automated FiO2 control provided by PRICO to manual control of FiO2. Study subjects will be randomly assigned to both study arms for 24 hours.

Study burden and risks

Both investigational interventions can be used as a standard practice in neonatal units. Therefore, the study is not expected to expose the subject to any significant risks. However, use of both methods of FiO2 control, might not be optimal for that subject at that time in their course of treatment. The risk of this is minimized in that, if such a problem were perceived, the care team attending the infant or the parent can request withdrawal from the study.

PRICO has the potential to improve the time a patient*s SpO2 values are within the target range and avoid both hypoxemia and hyperoxemia compared to manually adjustments of FiO2. Previous research showed that PRICO decreased SpO2 fluctuations and limited the duration of both hypoxemia and hyperoxemia. The investigation may provide information that will enhance the selection of optimal oxygen control and thus could improve the effectiveness of subject*s respiratory care following intervention. The results of the study are expected to improve respiratory care of infants in general. The device used in the investigation is bearing the CE mark and is used according to its intended use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

• Infants with respiratory insufficiency admitted to the NICU who require respiratory support and supplemental oxygen (FiO2 > 0.21) in one of 4 therapeutic categories (HFOV , CMV, Non-Invasive nasal mask, nasal cannula).
• Informed Consent Form obtained as per EC requirement.

Exclusion criteria

• Not expected to complete 48 hours of the current respiratory support therapeutic category
• Congenital anomalies
• Uncontrolled hemodynamics instability

• Severe airflow obstruction
• Intracranial hypertension
• Start of caffeine therapy within 12 hours of entering the study protocol
• Attending physician does not believe participation of the patient is in their best interest.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2022
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	fabian-PRICO
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-03-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04957472
CCMO	NL79179.018.21