

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 clinical 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 ($\text{FiO}_2 > 0.21$) 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 |