oxIdative stress in late preterM and term newborns with Persistent pulmonAry hypertension in the neonatal intensive Care uniT (IMPACT-study)

Published: 04-02-2025
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To investigate oxidative stress levels in the plasma and urine of late preterm and term newborns treated for PPHN in the NICU.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal and perinatal conditions
Study type	Observational invasive

Summary

ID

NL-OMON57289

Source
ToetsingOnline

Brief title
IMPACT-study

Condition

- Neonatal and perinatal conditions
- Neonatal respiratory disorders
- Vascular hypertensive disorders

Synonym
Persistent Pulmonary Hypertension of the Newborn; persistent high blood pressure in the lungs of the newborn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Infant, Newborn, Oxidative stress, Oxygen, Persistent Fetal Circulation Syndrome

Outcome measures

Primary outcome

The main study parameters are oxidative stress levels, quantified by the

concentration of 8-iso-PGF2α and malondialdehyde (MDA) in the plasma and urine.

Secondary outcome

Secondary parameters include the concentration and duration of supplemental

oxygen therapy, and the occurrence of hyperoxemia and hypoxemia.

Study description

Background summary

Persistent pulmonary hypertension of the newborn (PPHN) is a complication during neonatal transition characterized by sustained elevation in pulmonary vascular resistance (PVR), primarily affecting late preterm and term newborns. Treatment in the NICU often involves high concentrations of supplemental oxygen and inhaled nitric oxide (iNO) to reduce PVR and improve oxygenation. It has been well established that high concentrations of supplemental oxygen during resuscitation of late preterm and term newborns are harmful, but little is known about the potential harmful effects of liberal oxygen use once these newborns are admitted to the NICU.

Study objective

To investigate oxidative stress levels in the plasma and urine of late preterm and term newborns treated for PPHN in the NICU.

Study design

Single center, prospective, observational cohort study.

Study burden and risks

The risks associated with participating in the study can be considered negligible, and the burden can be considered minimal as blood and urine sampling are part of standard care in the NICU, eliminating the need for additional punctures. The maximum total additional volume of blood drawn for this study is less than the amount collected on the first day for standard care analyses. The urine that is sampled would otherwise be discarded. Due to the observational nature of this study, the included newborns will not directly benefit from participating in the study. However, previous research indicates that helping future patients is a significant factor motivating parents to consent to their newborns' participation in neonatal studies. The study population was selected because newborns with PPHN are unique among late preterm and term newborns in that they need extended periods of high concentrations of oxygen therapy. Unlike preterm newborns, there are no guidelines for oxygen use in these newborns, placing them at a particularly high risk of oxidative stress.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

1. Gestational age at birth >= 34 weeks.
2. Treatment with oxygen and inhaled nitric oxide (iNO) in the NICU of the LUMC for PPHN.

Exclusion criteria

1. Congenital malformations that affect the ability to adequately oxygenate (e.g., cyanotic congenital heart defects and congenital diaphragmatic hernia).
2. No arterial line in place as part of standard care.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2025
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	04-02-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL87541.058.24