Pulmonary inflammation and glucocorticoid sensitivity for the prediction of bronchopulmonary dysplasia (PRIDICT-BPD): A multicenter study

Published: 12-07-2021
Last updated: 17-01-2025

To develop a prediction model for BPD using a range of multimodal predictors assessed in the first two weeks of life.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal respiratory disorders
Study type	Observational non invasive

Summary

ID

NL-OMON50974

Source
ToetsingOnline

Brief title
Pulmonary Inflammation and Glucocorticoid Sensitivity in Preterm Infants

Condition

- Neonatal respiratory disorders

Synonym
Bronchopulmonary dysplasia, chronic lung disease of prematurity

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam Universitair Medische Centra
Source(s) of monetary or material Support: Amsterdam Reproduction & Development

Intervention

Keyword: Bronchopulmonary dysplasia, Glucocorticoïds, Premature infants, Pulmonary inflammation

Outcome measures

Primary outcome

Primary parameters:

1. Pulmonary inflammation, as assessed from volatile organic compounds (VOCs);

2. Adrenocortical output, as assessed from levels of cortisol, 17-OH

progesterone and 11-deoxycortisol;

3. Glucocorticoid tissue-sensitivity, as assessed from single-nucleotide

polymorphisms (SNPs) in the glucocorticoid receptor gene and

glucocorticoid-responsive genes involved in lung development.

Primary outcome:

The occurrence and severity of BPD.

Secondary outcome

Secondary outcome:

Neurocognitive development at 1 and 2 years of corrected age, as assessed from

eye tracking at the age (if available in participating center) and the Bayley

Scales of Infant Development, respectively.

Study description

Background summary

Extremely preterm infants (<30 weeks of gestation) who develop bronchopulmonary dysplasia (BPD) are at high risk of serious neurodevelopmental problems. Pulmonary inflammation is a key factor in the development of BPD. The adrenal-cortex hormone cortisol is known for its anti-inflammatory effects. In the first weeks of life preterm infants are unable to produce sufficient cortisol for the degree of inflammation, and due to the relative abundance of the precursor steroids 11-deoxycortisol and 17-OH progesterone, their tissues are relatively resistant to cortisol.
Both can result in insufficient damping of pulmonary inflammation. Prophylactic treatment with systemic corticosteroids is effective for the prevention of BPD, but has been associated with an increased risk of adverse neurocognitive development particularly among infants at low risk of BPD.
These findings warrant a more personal approach in corticosteroid treatment, targeted at high-risk infants. However, implementation of targeted treatment is held back by the poor performance of the available prognostic models for BPD development.
We propose a novel approach for the early identification of infant at risk of BPD by focusing on 3 major players in the development of BPD, namely 1. Pulmonary inflammation; 2. Adrenocortical output; and 3. Glucocorticoid tissue-sensitivity.
With these factors we aim to develop a prediction model for BPD using a multimodal predictors assessed in the first two weeks of life.

Study objective

To develop a prediction model for BPD using a range of multimodal predictors assessed in the first two weeks of life.

Study design

Multicenter prospective cohort study.

Study burden and risks

Improving outcomes in the growing population of preterm infants is one of the major challenges in neonatal care today. There are no burdens or risks associated with participation in this study. Blood will always be drawn at the same time as for routine clinical care, so that no additional vena puncture or heel stick procedures are required for this study. Furthermore, the decision to start treatment with corticosteroids will remain at the discretion of the treating physician. This study is specifically focused on infants born <30

weeks of gestation. Such infants have a very high risk of developing BPD, and generally have a poor prognosis in terms of survival and long-term outcome. Improving their prognosis is of the utmost importance.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Newborn infant born <30 weeks of gestation

Exclusion criteria

Major congenital anomalies, such as congenital heart and pulmonary defects, and major genetic anomalies.
Major surgery in the first 24 hours after birth

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-02-2022
Enrollment:	375
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-03-2022
Application type:	Amendment
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
CCMO	NL76476.029.21