PulmonaRy Inflammation and glucocorticoiD sensItivity for the prediCTion of BronchoPulmonary Dysplasia (PRIDICT-BPD): a feasibility study.

Published: 20-09-2019
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The objective of this study is to test whether the assays described above are feasible to predict bronchopulmonary dysplasia in premature infants.

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

Summary

ID

NL-OMON49781

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, locatie VUmc
Source(s) of monetary or material Support: Stichting Steun Emma

Intervention

Keyword: Bronchopulmonary dysplasia, Glucocorticoïds, Premature infants

Outcome measures

Primary outcome

* To test whether the assays described above are feasible in this patient group

Secondary outcome

* To test whether the outcomes on the assays are associated with the

development of BPD and the duration of respiratory support;

* To test whether the outcomes on these assays are associated with

pro-inflammatory markers;

Study description

Background summary

Preterm infants who develop bronchopulmonary dysplasia (BPD) are at high risk of cognitive impairments and cerebral palsy. The adrenal cortex of extremely preterm infants is immature, resulting in a cortisol level that is too low for the degree of illness. Novel data suggest that not only the production but also the action of cortisol is impaired in this group. Prophylactic treatment with systemic corticosteroids is effective for the prevention of BPD, but increases the risk of adverse neurodevelopment.

It is generally assumed that infants at high risk of BPD may benefit from prophylactic corticosteroids, whereas in low-risk infants the adverse effects of this treatment probably outweigh the beneficial effects. However, clinical prediction models for BPD lack accuracy.

We propose a novel strategy for the prediction of BPD that includes assessment of (1) adrenocortical output, (2) single-nucleotide polymorphisms (SNPs) in

corticosteroid-responsive genes expressed during lung development, and (3) pulmonary inflammation.

Therefore we will collect material post partum to test above assays. First cord blood and placental tissue will be collected after delivery. During admission on the neonatology intensive care unit whole blood and exhaled breath will be collected four times.

Study objective

The objective of this study is to test whether the assays described above are feasible to predict bronchopulmonary dysplasia in premature infants.

Study design

Prospectie follow-up study during the initial hospital admission.

Study burden and risks

Improving outcomes in the growing population of extremely preterm infants is one of the major challenges in neonatal care today. There are no burdens or risks associated with participation in this study. Cord blood will be collected after clamping the cord. And biopsy of placental material will take place after delivery. So for both procedures no adverse effects will be expected. Blood (cumulative amount: 2 ml over a 28 day period) 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.
Exhaled breath will be collected without loss of positive and expiratory pressure or respiratory support. Therefore, no additional risk is associated with this procedure.

Furthermore, the decision to start treatment with corticosteroids will remain at the discretion of the treating physician and will not be based on the assays being tested.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Newborn infant born <30 weeks of gestation

Exclusion criteria

Congenital anomalies of any kind
Major surgery within 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:	Recruitment stopped
Start date (anticipated):	28-10-2019
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	20-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2020
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

ID: 23788
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69893.029.19
OMON	NL-OMON23788