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

Gepubliceerd: 02-10-2020 Laatst bijgewerkt: 15-05-2024

Prediction of the development of bronchopulmonary dysplasia in preterm infants including assessment of the adrenal gland function and pulmonary inflammation.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23788

Bron
Nationaal Trial Register

Verkorte titel
PRIDICT-BPD study

Aandoening

Bronchopulmonary dysplasia

Ondersteuning

Primaire sponsor: Stichting Steun Emma
Overige ondersteuning: Stichting Steun Emma

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To test whether the assays described above are feasible in this patient group to develop a prediction model for BPD in the future.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Preterm infants (< 30 weeks of gestation) who develop bronchopulmonary dysplasia (BPD) are at high risk of cognitive impairments and cerebral palsy.
The adrenal cortex of 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. Both can result in insufficient damping of pulmonary inflammation, which is considered a key pathway in the development of BPD. Prophylactic treatment with systemic corticosteroids is effective for the prevention of BPD, but has been associated with increased risk of adverse neurocognitive development. It is generally assumed that infants at high risk of BPD may benefit from 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. glucocorticoid bioactivity, 3. singlenucleotide
polymorphisms (SNPs) in corticosteroid-responsive genes expressed during lung development, and 4. pulmonary inflammation.

Objective: To test whether the assays described above are feasible to develop a prediction model for BPD in the future.

Study design: Prospective follow-up study during the initial hospital admission.

Study population: Fifty infants born <30 weeks of gestation.

Intervention (if applicable): N/A

Main study parameters/endpoints: Determinants are: [1] adrenocortical output and [2] glucocorticoid bioactivity measured in (cord) blood at the day of birth and at postnatal days 3,
7, 14 and 28; [3] single-nucleotide polymorphisms in corticosteroid-responsive genes expressed during lung development measured in cord blood or placental tissue; and, [4] pulmonary inflammation, as assessed by volatile organic compounds (VOCs) in exhaled breath and interleukins in blood obtained at above time points. Outcomes are the rate and severity of BPD, and the level and duration of respiratory support.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. In addition to cord blood, 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. 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.

Doel van het onderzoek

Prediction of the development of bronchopulmonary dysplasia in preterm infants including assessment of the adrenal gland function and pulmonary inflammation.

Onderzoeksopzet

Postpartum, day 3, day 7, day 14 and day 28.

Onderzoeksproduct en/of interventie

NA

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Prematurity <30 weeks GA

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Major congenital malformation

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-10-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49781
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8941
CCMO	NL69893.029.19
OMON	NL-OMON49781

Resultaten