Extra zuurstof bij kinderen met bronchopulmonale dysplasia (BPD) na de neonatale intensive care periode: de SOS BPD studie

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Targeting a higher SpO2 (95% lower limit) in children with moderate-severe BPD from 36 weeks PMA and onwards, will possibly lead to superior growth of normal lung tissue (assessed indirectly by body weight) at 6 months corrected age, compared to a...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20710

Bron
Nationaal Trial Register

Verkorte titel
SOS BPD

Aandoening

bronchopulmonary dysplasia (BPD)
supplemental oxygen
oxygen saturation target
growth

In Dutch:
bronchopulmonale dysplasie
extra zuurstof
saturatie grens
groei

Ondersteuning

Primaire sponsor: Performer: Erasmus MC, Sophia Childrens Hospital
Overige ondersteuning: - Zon MW
- Longfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to investigate if targeting a higher SpO2 (i.e. 95% lower limit) leads to superior growth of normal lung tissue (assessed indirectly by body weight) at 6 months corrected age as compared to targeting a lower SpO2 (90% lower limit) in children with moderate-severe BPD from 36 weeks PMA and onwards

Toelichting onderzoek

Achtergrond van het onderzoek

Extreme preterm birth leads to an arrest in lung and pulmonary vascular development which may result in bronchopulmonary dysplasia (BPD). BPD is a chronic lung disease that leads not only to life-long respiratory issues, but also to adverse cardiovascular and neurodevelopmental outcomes. Moreover, the impact on parents of taking care of a child with BPD can be significant,with increased stress, low sleep quality and depressive symptoms, all having an impact on their quality of life. In the Netherlands, BPD affects approximately 500 infants each year, of whom two thirds have the moderate to severe form of the disease, which means that they are still oxygen-dependent at 36 weeks postmenstrual age (PMA).

The main treatment for BPD is supplemental oxygen. Several randomised controlled trials have assessed a liberal versus a restricted use of supplemental oxygen in extreme preterm infants in the first weeks of life on major outcomes such as death, development of BPD or retinopathy of prematurity, and neurodevelopment. However, no study has ever examined the optimal oxygen saturation (SpO2) target that should be obtained by supplemental oxygen in children with established BPD after 36 weeks PMA. This target may be different from the established SpO2 targets in the first weeks of life, as at 36 weeks PMA vulnerability to oxidative stress (and e.g. development of retinopathy of prematurity) has most probably decreased. Moreover, alveolar growth only starts from approximately 34 weeks of gestation, announcing a new era in lung growth.

Due to the lack of studies, the Dutch BPD guideline refrains from any recommendations on SpO2 targets in children with established BPD. This has resulted in wide practice variability between hospitals in lower SpO2 targets, with most hospitals accepting a lower SpO2 limit of 90%. However, this limit may be too low, because, according to a number of observational studies, supplemental oxygen may decrease respiratory symptoms, prevent pulmonary hypertension, be beneficial for neurodevelopment and improve weight gain if BPD is present. Importantly, in children with BPD, body weight during infancy has been positively associated with the amount of normal lung tissue as assessed with CT scans, and better lung growth is related to increased lung function in later life. Furthermore, poor weight gain is associated with increased vulnerability to infections and supplementary oxygen may reduce the risk for nosocomial infections and consequently for re-hospitalisation. On the other hand, hyperoxia (e.g. too much oxygen) may result in increased levels of reactive oxygen species and subsequent oxidative damage. This may negatively influence lung development but also the development of other organs such as the eyes and the brain. In short, too little oxygen may have detrimental effects on preterm children with BPD, while too much oxygen should also be avoided, and it is unknown where this balance lies between too little and too much oxygen.

Doel van het onderzoek

Targeting a higher SpO2 (95% lower limit) in children with moderate-severe BPD from 36 weeks PMA and onwards, will possibly lead to superior growth of normal lung tissue (assessed indirectly by body weight) at 6 months corrected age, compared to a lower SpO2 (lower limit 90%).

Onderzoeksopzet

- inclusion (36-38 weeks of gestational age)

- At 6 months corrected age

- At 12 months corrected age

Onderzoeksproduct en/of interventie

Children with moderate-severe BPD from 36 weeks PMA and onwards, receiving supplemental oxygen, will be randomized with two parallel arms:

1. weaning of supplemental oxygen based on SpO2 lower limit ≥ 95%

2. weaning of supplemental oxygen based on SpO2 lower limit ≥ 90%.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- born < 32 weeks of gestational age

- oxygen need for >= 28 days from birth until 36 weeks of PMA

- moderate or severe BPD at 36 weeks postmenstrual age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Significant congenital heart disease (not being persisting ductus arteriosus, small atrial septal defect, ventricular septal defect)

- pulmonary hypertension treated with sildenafil or bosentan

- retinopathy of prematurity for which the ophthalmologist recommended a patient specific

SpO2 target

- congenital malformations of the lung or airways

- severe acquired upper airway abnormalities like subglottic stenosis necessitating endotracheal intubation

- interstitial lung disease

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	196
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7149
NTR-old	NTR7347
Ander register	ZonMw // Longfonds : 80-84300-98-83013 // 4.1.17.162

Resultaten