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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20710

Source
Nationaal Trial Register

Brief title
SOS BPD

Health condition

bronchopulmonary dysplasia (BPD)
supplemental oxygen
oxygen saturation target
growth

In Dutch:
bronchopulmonale dysplasie
extra zuurstof
saturatie grens
groei

Sponsors and support

Primary sponsor: Performer: Erasmus MC, Sophia Childrens Hospital
Source(s) of monetary or material Support: - Zon MW

- Longfonds

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary objectives of this study are:

- To determine if targeting a higher SpO2 (i.e. 95% lower limit) translates into better body weight and height at 12 months corrected age, less health care consumption and better quality of life of the parents or caregivers.

- To determine if a strategy aiming at a lower limit of SpO2 of >= 95% is cost-effective.

In a subgroup of children:

- To determine if a strategy aiming at a lower limit of SpO2 of >= 95% translates into better lung function (lower lung clearance index) and/or better lung structure as assessed with CT scans.

- To determine if a strategy aiming at a lower limit of SpO2 of >= 95% translates into less pulmonary hypertension and/or better right ventricle systolic function.

Study description

Background summary

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.

Study objective

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%).

Study design

- inclusion (36-38 weeks of gestational age)

- At 6 months corrected age

- At 12 months corrected age

Intervention

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%.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-10-2018
Enrollment:	196
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	10-07-2018
Application type:	First submission

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
NTR-new	NL7149
NTR-old	NTR7347
Other	ZonMw // Longfonds : 80-84300-98-83013 // 4.1.17.162

Study results