Hypoxic challenge test in preterm infants

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25183

Source
NTR

Brief title
TBA

Health condition

Bronchopulmonary dysplasia
Prematurity
Pulmonary hypertensive disorders

Sponsors and support

Primary sponsor: Performer: Erasmus MC - Sophia Childrens Hospital
Source(s) of monetary or material Support: Stichting Sophia Kinderziekenhuis Fonds

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to investigate the predictive value of the hypoxic challenge test for respiratory morbidity (i.e. hypoxia in respiratory infections and need for hospital admission) in the six months following the test.

Secondary outcome

Secondary objectives of this study are:

- The relation of the HCT result and presence of pulmonary hypertension.
- Success/failure rate of the hypoxic challenge test (percentage of children that succeed or fail the test)
- Differences between groups (severe, mild-moderate or no BPD)
- Degree of right ventricular function related to the HCT outcome
- Polysomnography outcomes (Apnoea Hypopnoea Index (AHI), Oxygen Desaturation Index (ODI), mean saturation) and CT-scan score (% normal lung tissue, % hypo- and hyperattentuation, as assessed by PRAGMA BPD score) related to the HCT outcome.

Study description

Background summary

Rationale: Preterm birth is a risk factor for cardiopulmonary complications later in life and this risk is even more pronounced in children with bronchopulmonary dysplasia (BPD). Currently, there is a lack of feasible function tests to investigate pulmonary and pulmonary vascular function in infants after preterm birth. This is however the best age to start treatment, prevention and follow-up, since most problems (such as hypoxic incidents) occur in early life.
The hypoxic challenge test (HCT) is currently used as a pre-flight assessment for infants and children with chronic lung disease. It is actually a test that, because of creating a hypoxemic environment, challenges ventilation, diffusion and pulmonary vasoreactivity. Therefore, we hypothesize that in preterm born children with or without BPD, the HCT test is actually a function test for the pulmonary and pulmonary vascular system. When combined with echocardiography, pulmonary hemodynamics can be evaluated. Children who do not pass the hypoxic challenge test have an impaired cardiopulmonary function and are at risk for hypoxemic events (such as lower viral airway infections) and pulmonary hypertension.

Objective: The primary objective is to assess the hypoxic challenge test, combined with echocardiography, as a function test for the pulmonary and pulmonary vascular system in preterm born children with and without bronchopulmonary dysplasia.
Secondary objectives are the rate of success or failure of the test in preterm born children (with or without BPD), correlations of the HCT result with later respiratory morbidity, hospital admissions, right ventricular function and pulmonary hypertension. For children with severe BPD a polysomnography (PSG) and a chest CT are standard of care. The differences between children who fail and do not fail the HCT in polysomnography outcomes and chest CT scores will be assessed.

Study design: This is a prospective observational two-year pilot study in preterm born children (<30 weeks of gestational age) at six months corrected age. The children will undergo a hypoxic challenge test in a body plethysmograph. The test is preceded by a cardiac ultrasound to determine structural abnormalities, pulmonary vascular resistance and

right ventricular function. Immediately after the hypoxic challenge test, additional echocardiographic images will be obtained to determine pulmonary vascular reactivity and right ventricular function to hypoxia.

Study population: Children born <30 weeks gestation will be recruited when they attend standard neonatal follow up at Erasmus MC-Sophia Children's Hospital at 6 months corrected age. We intend to include : 1) 20 children with severe BPD; 2) 20 children with mild or moderate BPD; 3) 20 children without BPD.

Main study parameters/endpoints: Primary endpoints are the predictive value of the test for respiratory morbidity (i.e. hypoxia during respiratory infections and need for hospital admission) in the six months following the test. Also the relation of the HCT result and presence of pulmonary hypertension is one of the primary endpoints. .
Secondary endpoints are success and failure rate (failure rate meaning: not passing the test) per group, and presence of pulmonary hypertension, right ventricular function, chest CT score and polysomnography outcomes related to the HCT result.

Study objective

We hypothesize that the hypoxic challenge test, in combination with echocardiography, is a function test for pulmonary and pulmonary vascular capacity in preterm born children with and without bronchopulmonary dysplasia. Furthermore we hypothesize that the results of the hypoxic challenge test are correlated with morbidity during respiratory tract infections (desaturation, need for supplemental oxygen) and hospital admissions, and that there is a correlation between results of the hypoxic challenge test and right ventricular function.

Study design

At six months corrected age

Intervention

Children born <30 weeks gestational age with mild-moderate, severe or no BPD will undergo a hypoxic challenge test in a bodyplethysmograph at six months corrected age. The test is preceded by a cardiac ultrasound to determine structural abnormalities, pulmonary vascular resitance and right ventricular function. Immediately after the hypoxic challenge test, additional echocardiographic images will be obtained to determine pulmonary vascular reactivity and right ventricular function to hypoxia.

Contacts

Public
Erasmus MC - Sophia Kinderziekenhuis
Stephanie Balink

0650033994
Scientific
Erasmus MC - Sophia Kinderziekenhuis
Stephanie Balink

0650033994

Eligibility criteria

Inclusion criteria

- Born < 30 weeks gestation

- Diagnosis of:
o Severe BPD: ≥28 days of supplemental oxygen requirement at 36 weeks postmenstrual age and need for supplemental oxygen >30% and/or positive pressure (invasive ventilation, CPAP or HFNC) OR
o Mild-moderate BPD: ≥28 days of supplemental oxygen requirement at 36 weeks postmenstrual age and breathing room air (mild) or need for <30% supplemental oxygen (moderate) OR
o No BPD: <28 days of supplemental oxygen requirement at 36 weeks postmenstrual age

- Included in the long term neonatal or BPD follow up program of Erasmus MC

- Written informed consent by parents and/ or caregivers

Exclusion criteria

- Current supplemental oxygen requirement
- Congenital heart disease with hemodynamic consequences
- Pulmonary hypertension requiring medication
- Significant respiratory disease other than BPD

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-05-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52578
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7756
CCMO	NL68935.078.19

Register	ID
OMON	NL-OMON52578

Study results