The hypoxic challenge test in preterm infants with or without bronchopulmonary dysplasia: a test for pulmonary and pulmonary vascular function?

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52578

Source
ToetsingOnline

Brief title
Hypoxic challenge test in preterm infants

Condition

- Other condition
- Neonatal respiratory disorders
- Vascular hypertensive disorders

Synonym
chronic lung disease of prematurity. Pulmonary hypertension, high bloodpressure in the blood vessels of the lung., Prematurity, preterm birth. Bronchopulmonary dysplasia

Health condition

Vroeggeboorte

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Sophia Kinderziekenhuis Fonds

Intervention

Keyword: Bronchopulmonary dysplasia, Hypoxic challenge test, Prematurity, Pulmonary vascular disease

Outcome measures

Primary outcome

Primary endpoints are the predictive value of the test to predict 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.

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Secondary outcome

Secondary endpoints are success and failure rate (not passing the test) per

group, and degree of pulmonary hypertension, right ventricular function, chest

CT score and polysomnography outcomes related to the HCT result.

Study description

Background summary

Preterm birth is a risk factor for respiratory and cardiovascular complications

later in life and this risk is even more pronounced in children with bronchopulmonary dysplasia.
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 the early life years.
The hypoxic challenge test is a test that challenges ventilation, diffusion and pulmonary vasoreactivity. Therefore, we hypothesize that in preterm born children with or without bronchopulmonary dysplasia, the hypoxic challenge 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.

Study 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), relation of the HCT outcome with right ventricular function. For children with severe BPD: the difference between children who fail and do not fail the HCT, in polysomnography outcomes and chest CT scores.

Study design

This is a prospective observational two-year pilot study in preterm born children (<32 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 burden and risks

The burden and risks associated with participation are very low. No extra visits to the hospital are required; the standard outpatient clinic contact will be prolonged by around 60 minutes. Both the HCT as well as the cardiac ultrasound are non-invasive tests and carry no risk (cardiac ultrasound) or a risk of a sh6rt desaturation (HCT) to a lowest value of 85%, which has no clinical consequences.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)

Inclusion criteria

- Born <32 weeks gestation
- Diagnosis of:
== Severe BPD, or
== Mild-moderate BPD, or
== No BPD
- 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2019
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	22-11-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 25183
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68935.078.19
OMON	NL-OMON25183