Long-term Outcome of Bronchopulmonary Dysplasia * Focus on Cardiovascular Health

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Primary objective: Part A: MR cardiopulmonary exercise protocol validation: To validate the protocol of the CMR-ergometer against conventional ergometers in young healthy adultsPart B: CMR exercise study To examine cardiorespiratory structure and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON47123

Source
ToetsingOnline

Brief title
MRI-exercise study

Condition

- Heart failures
- Neonatal respiratory disorders

Synonym
cardiovascular health, chronic lung disease in premature babies

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bronchopulmonary dysplasia, cardiovascular

Outcome measures

Primary outcome

Part A: MR cardiopulmonary exercise protocol validation:

The main study parameter is the increase in oxygen consumption of subjects in relation to workload increase during a exercise test on a MR-ergometer and on a conventional ergometer.

Part B: CMR exercise study:

The main study parameter is stroke volume of the right ventricle.

Secondary outcome

Part A: MR cardiopulmonary exercise protocol validation:

Other parameters are maximal heart frequency, CO2 production, respiratory coefficient.

Part B: CMR exercise study:

Other study parameters are exercise capacity (peak oxygen uptake, VO2max) and several parameters for assessment of lung function (forced expired volume in 1 second, FEV, total lung capacity, TLC, fractional residual capacity, FRC, diffusion capacity for carbon monoxide, DLCO), and assessment of cardiac function and structure (e.g. heart ventricular mass/volume ratio, tricuspid regurgitation velocity, heart ventricular longitudinal strain and ejection

fraction).

Study description

Background summary

BPD is associated with a variety of long term health problems, including cardiovascular problems and exercise intolerance. However, only a few studies evaluate cardiovascular outcomes of BPD. In this study, we combine exercise testing with cardiac magnetic resonance (CMR) imaging to evaluate exercise capacity, but also to examine if exercise capacity correlates with cardiorespiratory structure and function. We will use a MRI-compatible ergometer (MR-ergometer). However, the exercise protocols of exercise tests performed on the supine MR-ergometer are not yet validated against the exercise protocols of exercise tests performed on a conventional ergometer. When well validated, this may potentially identify a group of adolescent survivors of BPD with an increased risk for cardiovascular events later in life, thereby contributing disproportionately to the burden of adult cardiovascular disease in the future. Our future perspective is to develop an exercise training program tailored for this specific patient group.

Study objective

Primary objective:
Part A: MR cardiopulmonary exercise protocol validation:
To validate the protocol of the CMR-ergometer against conventional ergometers in young healthy adults

Part B: CMR exercise study
To examine cardiorespiratory structure and function during submaximal exercise in adolescent survivors of extreme prematurity with/without BPD, to potentially reveal subtle dynamic abnormalities that are not apparent on conventional static tests.

Secondary objectives:
1) To study the exercise capacity of adolescent survivors of extreme prematurity with/without BPD
2) To determine if the diagnosis of BPD in the neonatal phase impose additional impairments in exercise capacity, cardiac function and/or structure in adolescent life

Study design

Follow-up study in Erasmus MC/ Sophia Children's Hospital, Rotterdam.

Study burden and risks

Part A: MR cardiopulmonary exercise protocol validation:
Participants need to visit the hospital twice. They will fill in a questionnaire, and undergo two exercise tests. One on the MR-ergometer and one on a conventional ergometer. Tests will take place on separate days, with at least three days between tests. Participants are asked not to perform intense physical ectivity two days before the tests.

Part B: CMR exercise study:
For the present study, patients need to visit the hospital twice. The first visit, they will undergo a conventional cardiopulmonary exercise test (CPET) and three pulmonary function tests. The second visit they will undergo an echocardiogram, ECG and a CMR will be performed at rest and during exercise. In addition, for study purposes patients need to fill in two questionnaires. For the exercise CMR, no breath-holds or ECG gated sequences can be used. Therefore a real-time sequence is needed. Some of these sequences are in development by GE (investigational sequences).
For the investigational sequences such as real-time SSFP sequence (radial SSFP) it has been verified that they do not affect the safe operation of the MRI scanner, but they have not been validated as effective for diagnostic use. All other sequences utilized in this study are commercially available. The investigational sequences will be implemented on a commercially available 1.5 Tesla GE Healthcare MRI scanner. A safety declaration of GE is available.

Contacts

Public
Erasmus Medisch Centrum, Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Erasmus Medisch Centrum, Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Healthy control group (n<=36; 16 for Part A, 20 for Part B); Young adults born a term at a gestational age * 37 weeks, age 18-25 years. For Part B, if possible, siblings of the participants of the preterm or BPD group are asked to participate to reduce potential lifestyle and socio-economic confounding effects.
2. Preterm group (n<=20, for Part B); Young adults born prematurely at a gestational age * 30 weeks, not diagnosed with BPD in the neonatal phase, age 18-25 years.
3. BPD group (n<=20, for Part B); Young adults born prematurely at a gestational age * 30 weeks, diagnosed with BPD in the neonatal phase, age 18-25 years. BPD is defined as oxygen dependency 28 days after birth. The severity of disease depends on the need of oxygen at 36 weeks of corrected gestational age; mild BPD no supplemental oxygen at 36-week, moderate BPD * 30% of supplemental oxygen, and severe BPD mechanical ventilation and/or oxygen >30 %.

Exclusion criteria

- Known acquired or congenital hemodynamically significant heart disease (except heart disease as a consequence of pulmonary hypertension)
- Pulmonary disorders other than BPD
- Kidney disorders
- Neurodevelopmental disabilities that would prevent cooperation with CPET and/or CMR imaging.
- Absence of written informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2018
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-08-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-12-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL56898.078.16