Evaluation of aortic elastic properties in the long-term follow-up of surgical and catheter interventional closure of the persistent ductus arteriosus

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON29770

Source
ToetsingOnline

Brief title
Aortic elastic properties after PDA closure

Condition

- Cardiac and vascular disorders congenital

Synonym
Patent ductus arteriosus, patent vessel between aorta and lung artery, persistent ductus arteriosus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: aorta, elastic properties, long-term follow-up, Persistent ductus arteriosus (PDA)

Outcome measures

Primary outcome

MRI-scanning:

difference in aortic distensibility between patients and controls.

Genetic testing:

presence of a predisposing mutation known to be associated with inheritable

aortic dissection and/or PDA.

Secondary outcome

not applicable

Study description

Background summary

Ductal closure by the means of catheter intervention is nowadays the standard treatment for PDA. Clinical follow-up is normally discontinued after documentation of a succesfull intervention. Data from animal studies suggest, that there might be a subgroup of patients in which the PDA is part of a more complex vascular disease. These patients might profit from specific cardiovascular follow-up. Aim of the study is to identify the patients at risk for aortic aneurysms after PDA-closure. In the past MRI has proven to be a reliable diagnostic tool to investigate cardiovascular morfology and function. In adolescents and young adults quality of echocardiographic images decreases. The advantage of MRI imaging lies in its non-invasive nature and reproducibility. Therefore MRI is an attractive method for this longitudinal

study.

Study objective

1. To identify the patients at risk for aortic aneurysms after PDA closure.

We expect to find a decreased distensibility of the aorta in this subgroup of patients which will be examined by MRI. Besides the functional MRI study genetic testing of the patients is intended. Predisposing mutations and DNA loci known to be associated with inheritable aortic dissection and/or PDA.

2. To gain longterm data on possible aortic changes in patients after PDA-closure.

3. To stratify the patientgroup with PDA by the need of follow-up after ductal closure.

Study design

prospective patient-based study

Study burden and risks

Burden of the patient/parents:
1. completion of a questionnaire: burden minimal, no risks.
2. MRI-scan: burden minimal: 2 hours study-time plus travel to the hospital, no risks in probands without contraindications.
3. DNA-study: burden minimal: venipuncture: risk low, genetic counseling will be offered to patients with clinical relevant results.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis of PDA or MARFAN, > 12 year

Exclusion criteria

1. Hemodynamically relevant residual cardiac anomalies
2. Genetic syndromes other than MARFAN
3. Contraindication against MRI-scanning (arrhythmias, pacemaker implantation, claustrophobia)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2006
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL13585.058.06