The Effect of Renin-Angiotensin System Inhibition on Aortic Dilatation Rate in Patients with Coarctation of the Aorta.

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Ethical review	Approved WMO
Status	Suspended
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON48859

Source
ToetsingOnline

Brief title
ASPECT study.

Condition

- Congenital cardiac disorders

Synonym
Aortic coarctation, narrowing of the aorta

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Aortic coarctation, Aortic dilatation, Cardiac magnetic resonance imaging, Renin-angiotensin system inhibition

Outcome measures

Primary outcome

CMR:

- Dilatation rate of the aortic root and ascending aorta (mm/year)

Secondary outcome

CMR:

- Total aortic volume expansion (mL/year)

- Myocardial fibrotic size by T1-mapping and LGE (% of LV myocardium)

- Pulse wave velocity (m/s)

- Distensibility of ascending aorta (mmHg*1)

- Left and right ventricular ejection fraction (%)

- Longitudinal strain in 2- and 4-chamber long-axis views (%)

- Circumferential strain at apical, mid-ventricular and basal LV levels (%)

- LV end-diastolic volume indexed to body surface area (mL/m2)

- LV end-systolic volume indexed to body surface area (mL/m2)

- LV mass indexed to body surface area (g/m2)

- Septal and posterior wall thickness (cm)

Transthoracic echocardiography:

- Aortic diameter at the level of the aortic root (mm)

- Peak-to-peak systolic pressure gradient across coarctation site (mmHg)

- Peak velocity at coarctation site (m/s)

- E/A ratio

Exercise testing:

- Peak exercise systolic blood pressure (mmHg)

24-hour ambulatory blood pressure monitoring:

- Mean 24-hour systolic blood pressure (mmHg)

- Mean 24-hour diastolic blood pressure (mmHg)

Study description

Background summary

Patients with coarctation of the aorta (CoA) are at high risk to develop an ascending aortic aneurysm, which is associated with early mortality. Since renin-angiotensin system (RAS) inhibitors have shown promising effects in reducing aortic dilatation in patients with Marfan syndrome, we seek to determine whether RAS inhibition may also prevent aneurysm formation in CoA patients. Moreover, we are interested whether diffuse left ventricular (LV) fibrosis can be detected in CoA patients to discriminate between different potential mechanisms underlying LV hypertrophy in these patients.

Study objective

Our main objective is to evaluate the effect of RAS inhibition on ascending aortic dilatation rate by cardiac magnetic resonance (CMR) imaging in CoA patients, and compare this to CoA patients without RAS inhibition. As secondary objectives, we aim to determine the presence and pattern of LV fibrosis by CMR T1-mapping compared to late gadolinium enhancement (LGE) and assess whether hemodynamic and structural parameters are associated with LV fibrosis.

Study design

Multicenter, observational, retrospective cohort study with in part prospectively collected data. With regard to the assessment of LV fibrosis and

potentially associated parameters (i.e. secondary objectives), a cross-sectional design is used.

Study burden and risks

CMR, transthoracic echocardiography, exercise testing, and 24-hour ambulatory blood pressure monitoring are considered as standard of care. For study purposes, the CMR protocol is extended by T1-mapping and LGE with administration of gadolinium-based contrast agents. These agents have a widespread clinical use and adverse reactions and side effects are rare. Since pre-existent severe renal dysfunction may deteriorate after administration of gadolinium contrast, patients a with creatinine clearance <30 mL/min/1,73 m² will be excluded from this study. T1-mapping necessitates hematocrit measurement and therefore a 3 mL blood sample will be drawn by venous puncture. Using the NFU risk classification instrument, we consider the risks associated with participation in this study as negligible.

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

- Subject has been diagnosed with CoA.
- Subject has previously undergone a surgical or transcatheter (balloon dilatation or stenting) intervention for CoA.
- A previous CMR has been performed on the subject.
- Subject is at least 16 years of age.
- Subject is competent to understand the performed procedures, the potential hazards associated with these procedures, and to provide written informed consent.

Exclusion criteria

- Subject with thoracic aortic dissection prior to study period.
- Subject who underwent an intervention for an aneurysm of the ascending aorta prior to study period.
- Subject is currently pregnant or has been pregnant during the study period.
- Subject has a medical condition which, in the opinion of the investigator, could adversely affect the subject*s safety and/or the interpretation of the results.
- Subject with a contraindication for CMR with administration of gadolinium-based contrast agent:
• Cardiac pacemaker or implanted cardioverter defibrillator not compatible with CMR.
• Electronic device or implant, such as cochlear implant or insulin pump.
• Past adverse reaction to gadolinium-based contrast agents.
• Severe renal insufficiency (creatinine clearance <30 mL/min/1,73 m^2).
• Known claustrophobia.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	15-07-2019
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	03-04-2019
Application type:	First submission
Review commission:	METC NedMec

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	NL66205.041.18