Pulse-Wave Velocity Measurement in Patients with Marfan Syndrome: Automated and Non-Invasive Assessment of the Regional Vascular Status for Risk Stratification

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

Summary

ID

NL-OMON30274

Source
ToetsingOnline

Brief title
Acquisition of the Elasticity of the aorta with MRI

Condition

- Cardiac and vascular disorders congenital
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
disturbed compliance of the vascular status, Marfan

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Aorta, Magnetic Resonance Imaging, Marfan Syndrome

Outcome measures

Primary outcome

This non-invasive approach will demonstrate to be a clinically applicable,

accurate and reproducible method with prognostic value for the vascular status

of the aorta.

Secondary outcome

not applicable

Study description

Background summary

Recent publications emphasize the importance of measuring the Pulse-Wave Velocity (PWV) in the aorta as an indicator of arterial stiffness in vascular disease. Echo Doppler and intra-vascular pressure measurements are currently the methods of choice to derive the PWV. However, accurate pressure measurements require an invasive procedure. Using echo Doppler, the course along the aorta, which the wave has to propagate (needed for PWV calculation), is estimated from the distance between two measurement sites (i.e., the carotid and the iliac artery). This results only in crude estimation of the global PWV. Reproducibility and accuracy are questionable.
Several studies explored the possibilities of using velocity-encoded (VE) MRI to determine the PWV. MRI is an accurate and non-invasive modality from which a 3D-velocity vector field in vessels can be determined, without the need of modeling assumptions.
The availability of a diagnostic and prognostic tool to study areas in the aorta with regionally impaired wall compliance is very much desired, as these areas are at risk for dissection or aneurysm development. Such is the case in patients with Marfan syndrome. Marfan syndrome is an autosonomal dominant

connective tissue disorder concerning many systems, also with cardiovascular manifestations. The leading cause of premature death in these patients is aortic dissection due to progressive dilatation of the aortic root. Aortic stiffness is investigated as a potential predictor of aorta dissection and aneurysm development.

Study objective

Main objective of this study is to develop an MRI protocol from which regional PWV can be assessed. An automated image analysis tool, indispensable for fast, reproducible and observer-independent data processing will be developed. The technique will be validated with intra-arterial pressure measurements in a phantom study and in patients.

Study design

This four year study will be performed in four phases:
A. Scan optimization: a multi-directional VE MRI scan protocol with a high temporal resolution needs to be optimized for tracing the systolic wave front through the aorta.
B. Software development: the MRI acquisition results in large data sets (i.e., 1500-2000 images per patient). In order to make the analysis of these images and the quantification of PWV applicable in clinical routine, segmentation (contour detection) of the aorta in these VE MR images (needed for constructing the intra-aortic flow velocity vector field) has to be automated.
C. Validation: the accuracy of PWV MRI measurements will be determined by comparing MRI with intra-arterial pressure measurements in a phantom study and in patients selected for cardiac catheterization.
D. Application: the new MRI method will be applied in a patient study to test the prognostic value of PWV measurement. Fifty patients with Marfan syndrome, with proven regional impaired aortic wall compliance (i.e., with an implanted aortic graft), will undergo an MRI examination. A follow-up MRI examination two years later will provide insight on aortic events (i.e., local dilatation). For comparison, 25 healthy volunteers (age- and gender-matched with the patients) will be included.

Study burden and risks

The risks for the participating 25 patients in the validation part of the study are minimal. Patients will undergo additional intra-aortic pressure measurements during the angiographic procedure. During this angiogram, pressure measurements are already routinely performed in the left ventricle. Aditionally for this study, during pull back of the catheter, the pressure will be registered at 8-10 locations in the aorta. No additional catheter will be inserted, no additional contrast will be administered and no additional x-ray images will be acquired. One week after catheterization, patients will undergo

an additional MRI examination. For this, no contrast agent will be administered, and MRI is free from radiation, so this will not result in additional burden to the patient.
The risks for the participating 25 volunteers in the validation part of the study are also minimal. Volunteers will only undergo the MRI examination.
Finally, the risks for the participating 50 patients with Marfan syndrome in the application part of the study are minimal. These patients already routinely undergo MRI examinations at the AMC. When participating in this study, the patients will undergo this clinically needed MRI at the LUMC instead. Usually two weeks before this routine examination, patients will stop using beta blocker medication. Medication will start again after MRI examination. This procedure will also be followed for their MRI examination at the LUMC. The only additional examinations needed for this research study are two scans resulting in 15-20 minutes longer examination time compared to the routine MRI.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with Marfan syndrome with expected regionally impaired aortic wall compliance (eg. with an implanted aortic graft) will be recruited from the patient database at the AMC. Patients already undergoing an angiographic procedure, that are selected for additional pressure measurements and MRI, are recruited at the LUMC. Healthy volunteers will be age- and gender-matched to the Marfan patient population. Other inclusion criterion is the subject*s willingness to undergo (additional) MRI examinations at the LUMC.

Exclusion criteria

Exclusion criteria are the standard MRI exclusion criteria (pacemakers, cerebral vascular clips, metallic splinters in the eye, pregnancy, claustrophobia).

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL15852.058.06