

# Four-dimensional flow cardiac magnetic resonance imaging for the assessment of coarctation of the aorta, a monocenter, prospective, diagnostic cross-sectional study.

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1. To investigate non-invasive 4D flow CMR for the assessment of aortic arch stenosis and compare and correlate this to conventional imaging modalities and to three-dimensional rotational angiography (3DRA) with computational fluid dynamics (CFD). 2...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Congenital cardiac disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON43033

### Source

ToetsingOnline

### Brief title

4D flow CMR in coarctation of the aorta.

### Condition

- Congenital cardiac disorders

### Synonym

coarctation of the aorta, congenital heart disease

### 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:** 4D flow CMR, aorta, coarctation, computational fluid dynamics

## Outcome measures

### Primary outcome

- \* flow qualification in the aorta and across the four cardiac valves.
- \* flow quantification in the aorta and across the four cardiac valves (in mL).

### Secondary outcome

- \* wall shear stress.
- \* pressure difference.
- \* pulse wave velocity.
- \* turbulent kinetic energy.
- \* viscous energy losses.
- \* standardized flow parameters.
- \* peak velocity.
- \* acquisition time.
- \* post-processing time.
- \* Inter-observer agreement.
- \* Difference in stroke volumes over the cardiac valves in the absence of shunting or valvular regurgitation.

# Study description

## Background summary

Standard assessment of aortic coarctation (CoA) consists of static imaging techniques (diameter) and pressure measurements (measured invasively). The novel, four-dimensional flow cardiac magnetic resonance (4D flow CMR) technique allows for a more comprehensive evaluation of the thoracic aorta flow, including the site of coarctation. 4D Flow CMR provides a non-invasive method for the qualitative and quantitative characterization of blood flow and can be used to derive advanced hemodynamic measures without radiation burden. Hereby, 4D flow CMR provides an integrated imaging modality to fully understand the substrates of CoA, with the potential to improve patient identification, risk stratification, follow-up, and treatment, and to reduce unnecessary, invasive angiography.

## Study objective

1. To investigate non-invasive 4D flow CMR for the assessment of aortic arch stenosis and compare and correlate this to conventional imaging modalities and to three-dimensional rotational angiography (3DRA) with computational fluid dynamics (CFD).
2. To investigate 4D flow CMR for the assessment of flow across the cardiac valves and compare to conventional 2D CMR.

## Study design

Prospective, mono-center, diagnostic cross-sectional study.

## Study burden and risks

The only burden is a longer duration of the CMRm, with <10 minutes. This CMR is standard of care, as well as the follow-up CMR 1 month after intervention (if applicable). According to the risk classification advise of the Federation of University Medical centers (hulplijst risicoclassificatie uit NFU advies kwaliteitsborging mensgebonden onderzoek) the study has to be graded as negligible risk.

# Contacts

## Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100  
Utrecht 3584 CX  
NL  
**Scientific**  
Universitair Medisch Centrum Utrecht

Heidelberglaan 100  
Utrecht 3584 CX  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Subject is at least 12 years of age
- Subject is being (re-)assessed for (re-)coarctation aorta
- Individual agrees to have all study procedures performed, and is competent and willing to provide written informed consent to participate in this clinical study. ;In order to be eligible to participate in this study, a subject in the control group must meet all of the following criteria:
- Subject is at least 12years of age
- Subject (and parents/legal guardians if under 18 years of age) agrees to have CMR study procedures performed, and is competent and willing to provide written informed consent to participate in this clinical study.

### Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation

in this study:

- Subject is younger than 12 years of age.
- Subject has any serious medical condition, which in the opinion of the investigator, may adversely affect the safety and/or effectiveness of the participant or the study
- Individual is pregnant, nursing or planning to be pregnant.
- Individual has a known, unresolved history of drug use or alcohol dependency, lacks the ability to comprehend or follow instructions, or would be unlikely or unable to comply with study follow-up requirements.
- Refusal to be informed about potential additional CMR findings
- Subjects with an eGFR <30mL/min.
- Individual in control group has any condition that according to the investigators might influence aortic flow.
- Subjects with any contraindications for CMR:
  - a. The presence of implanted non-CMR-compatible cardiac pacemaker or implanted cardioverter defibrillator.
  - b. Implanted electronic devices like cochlear implants and nerve stimulators.
  - c. Patients who are unable to fit into the bore of the magnet.
  - d. Claustrophobia

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 19-10-2017

Enrollment: 30

Type: Actual

## Ethics review

Approved WMO

Date:	10-06-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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	NL57178.041.16