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Comparison of different techniques and different scanner types for visualization and quantification of aortic blood flow by cardiovascular magnetic resonance

Submission date
08/02/2018

Recruitment status
No longer recruiting

Registration date
15/03/2018

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Two-dimensional flow imaging in cardiac (heart) MRI is a standard technique and well established. However, it only measures blood flow volumes in one cross-sectional plane of the aorta, so it cannot give information about wall shear stress or maximum velocity. A newly developed sequence for cardiovascular MRI can be used to measure blood flow and its impact on surrounding tissue in three dimensions and over time (i.e. over one cardiac cycle) - the common name for the sequence is therefore 4D-Flow. Blood flow pattern, volume and velocity can all be measured. The wall-shear stress of the aorta (the largest artery) can be examined, showing where the aorta is affected and altered by cardiac pathology (heart disease). Different types of this sequence have been developed, and it can be used at MRI scanners of different field strengths. It is important to know whether there are differences in the results when using different sequences or MRI scanners. The aim of this study is to compare three different sequences and three different field strengths in healthy volunteers, and to compare all 4D-Flow exams to the reference of two-dimensional flow measurement.

Who can participate?
Healthy volunteers, aged over 18

What does the study involve?
Three different sequences and three different field strengths are compared in healthy volunteers. All 4D Flow scans are assessed to measure blood flow in the thoracic aorta, wall shear stress and peak velocity, and are compared with two-dimensional flow measurement.

What are the possible benefits and risks of participating?
Cardiac MRI is considered the gold standard for measuring heart function. Participants may benefit from a thorough, high-level examination of the heart. Results can - upon request - be made available to the participant. Any incidental pathological findings are communicated with the participant as well. Future patients may benefit from a useful diagnostic tool in clinical

routine. 4D Flow has been proven to provide additional information in certain pathologies and can help with guiding treatment. Standardization of the technique is crucial for its use in clinical routine. The risk of an MRI exam are generally small (seldom temporary dizziness and light flashes, ending with leaving the MRI scanner). The biggest risk centers around the fact that a magnetic field is induced to gather the images. Therefore, metallic (magnetic) objects are of risk, including objects within the body such as implants. This is a general limitation for the use of MRI and is therefore also applied in this study. People with any kind of implant or metal within or on the body cannot participate.

Where is the study run from?
Charité University Medicine Berlin (Germany)

When is the study starting and how long is it expected to run for?
June 2016 to March 2018

Who is funding the study?
Charité University Medicine Berlin (Germany)

Who is the main contact?
Prof. Jeanette Schulz-Menger

Contact information

Type(s)
Scientific

Contact name
Prof Jeanette Schulz-Menger

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

4D Comparison (internal study code)

Study information

Scientific Title
Impact of field strength (1.5, 3.0 and 7.0 Tesla) and sequence on quantification of aortic flow volumes, peak velocity and wall shear stress using 4D flow MRI

Study objectives
Application of different techniques for measurement of haemodynamics in the Aorta ascendens does not have a significant influence on quantitative parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics board of the Charité University Medicine Berlin Campus Mitte:
1. 1.5 Tesla and 3.0 Tesla: 09/11/2012, ref: EA 1/258/12
2. First amendment: 30/05/2014
3. 7.0 Tesla: 25/08/2009, ref: EA 1/054/09

Study design
Observational feasibility study

Primary study design
Observational

Secondary study design
Feasibility study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Healthy volunteers without any known cardiac disease

Interventions
This is an observational study comparing three different techniques of visualization of blood flow in the aorta ascendens at three different cardiac MRI scanners with different field strengths (1.5 Tesla, 3.0 Tesla, 7.0 Tesla) in healthy volunteers. It serves at the same time as a feasibility study of this particular technique at 7.0 Tesla cardiac MRI.

Three different sequences and three different field strengths (1.5 Tesla, 3.0 Tesla and 7.0 Tesla) are compared in 10 healthy volunteers. All 4D-Flow exams are also compared to the reference of two-dimensional flow measurement. All 4D Flow scans are assessed as follows: blood flow in the thoracic aorta is visualized, forward-, backward- and net- flow is quantified. Wall shear stress and peak velocity are visualized and quantified. In the reference two-dimensional flow measurement forward-, backward- and net-flow is quantified.

Intervention Type
Other

Primary outcome measure
Blood flow volume in the thoracic aorta in each tested MR sequence over one cardiac cycle measured by three-dimensional cardiac magnetic resonance

Secondary outcome measures
Velocity of the blood flow and wall shear stress in the ascending aorta in each tested MR sequence over one cardiac cycle measured by three-dimensional cardiac magnetic resonance

Overall study start date
01/06/2016

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Age > 18 years
2. Written consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Any known cardiac disease
2. Contraindication to CMR

Date of first enrolment
01/11/2016

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
Germany

Study participating centre
Working Group on Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center a joint cooperation between the Charité University Medicine Berlin and the Max-Delbrueck Center for Molecular Medicine, and HELIOS Klinikum Berlin Buch, Department of Cardiology and Nephrology, Berlin, Germany
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Sponsor information

Organisation
Charité University Medicine Berlin

Sponsor details
Working Group Kardiale MRT Lindenberger Weg 80
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Sponsor type
University/education

Website
http://www.cmr-berlin.org

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité – Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal, probably within the next year.

Intention to publish date
12/02/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection laws in Germany. However, upon request methodology and dataset structure can be shared.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Retrospective analysis using study data to compare the results of two different commercially available software packages and their impact on different hemodynamic parameters	27/09/2024	17/06/2025	Yes	No
Results article		04/08/2020	17/06/2025	Yes	No