The heart in 3D - towards Non-Breath-Hold Cardiac MR to improve and accelerate myocardial function and tissue assessment (3DCMR)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON57265

Source
ToetsingOnline

Brief title
3DCMR

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart failure, myocardial ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Radiologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D perfusion imaging, 4D cine imaging, Cardiovascular MRI

Outcome measures

Primary outcome

The primary objective is to evaluate the image performance of the novel developed non BH 3D cardiovascular scan technique and the use of adaptive-CS-network in patients presenting with cardiovascular disease for the following CMR applications:

- Cardiac anatomy and cine imaging
- Cardiac perfusion imaging
- Late gadolinium enhancement (LGE)
- Mapping techniques including T1/T1rho/T2/T2*-mapping
- Cardiovascular flow imaging

Secondary outcome

Comparison with the conventional CMR acquisition and scan times.

Study description

Background summary

Cardiac magnetic resonance (CMR) has become an established, non-invasive imaging technique for the diagnosis and risk stratification of many cardiovascular diseases. There is a wide variety of CMR applications and techniques to evaluate and understand myocardial and vascular function and disease. The acquisition of current standard CMR scans, which require multiple breath holds (BH), can easily increase up to 1 - 1.5 hours. These relatively long scan times with the breath holds remain a challenge for patients and hospitals, limiting the accessibility of cardiac MRI. Reducing the total scan

time and eliminating breath holds will improve patient experience and make CMR future-proof. The new 3D cardiac MRI sequence enables free-breathing acquisitions without the necessity of multiple preparatory planning scans with preserved image quality. An iterative reconstruction methods is used by using the adaptive compressed sensing (CS) network. This can significantly reduce total scan time.

Study objective

We aim to reduce total scan time and accelerate the conventional acquisitions in patients presenting with cardiovascular disease by evaluating the novel developed non BH 3D cardiovascular scan technique and the use of the adaptive-CS-network for CMR.

Study design

Patients who are referred and eligible for cardiovascular MR by their cardiologist will be asked to participate. A standard clinical cardiovascular MRI protocol will be performed. After informed consent additional 3D CMR acquisitions will be added of maximal 15 minutes. No additional or other medication or contrast agents are administered. No special aftercare is needed. After the scan the patient can leave the hospital and will receive further clinical care from their own physicians following standard clinical procedure. Imaging processing and results of the 3D CMR imaging data will be compared with the standard scans used in regular clinical setting to assess and compare image performance and accuracy and total scan times.

Study burden and risks

We aimed to minimize burden for participants as much as possible. The participants will not receive any additional contrast fluids or other invasive measurements such as blood tests other than is necessary in the clinical setting to be able to address the question of the referring clinician. The risk associated with an additional scan time of 15-minutes is considered to be minimal. The remaining risks for the participants are the usual risks for a MRI scan and are minimized by the exclusion criteria and standardized MR safety protocols from the Radiology department. We consider the remaining risks neglectable for the participants of this study.

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

- Eligable for cardiac MR assessment
- Age >= 18 years
- Written informed consent

Exclusion criteria

- Exclusion criteria for MRI (claustrophobia, pacemaker, metal implants, etc.)
- A psychiatric, addictive or any other disorder that compromises the subjects ability to understand the study content and to give written informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	250
Type:	Anticipated

Medical products/devices used

Generic name:	MRI scanner;4D FBWH patch R57
Registration:	No

Ethics review

Approved WMO

Date:	20-01-2025
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	NL85313.058.24