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Changes in the accuracy of synchronisation of image acquisition and the heart cycle in ultra-high-field cardiovascular magnetic resonance, by utilising different placement positions of the electrocardiogram

Submission date	Recruitment status	[ ] Prospectively registered
26/08/2019	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
22/11/2019	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
03/08/2021	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The synchronisation of the heart cycle with image acquisition is essential in cardiovascular magnetic resonance applications. The standard method utilises the vector cardiogram (VCG) generated from different electrocardiogram (ECG) leads to trigger image acquisition. Higher magnetic field strengths lead to increased signal to noise ratio in MRI and are therefore promising for improving the diagnostic accuracy of the method, as well as for the development of new techniques. It was shown that the VCG acquired with the standard electrode placement is sufficient for field strengths up to 3T. At 7T, however, an artefact called the magnetohydrodynamic effect, severely distorts the ECG trace to the point where trigger detection is no longer feasible.
The aim of this study is to investigate the influence of different standardised electrode placements on trigger detection accuracy for different field strengths and sequences.

Who can participate?
Healthy volunteers without known cardiac disease

What does the study involve?
Participants will be scanned at clinical and ultra-high-field strengths and with different sequences for the standardised electrode placements. The impact of the electrode placement positions on trigger accuracy shall be evaluated

What are the possible benefits and risks of participating?
Cardiac MRI is considered the gold standard for the interpretation of cardiac function. Any incidental, pathological findings would be communicated with the participant.
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. This does also concern objects within the body (such as implants). This is a general limitation for the use of MRI and is therefore also applied on our study population. Any kind of implants or metal within or on the body is an exclusion criterion. If it is uncertain, if the participant had any kind of implant or metal within the body, he/she is excluded as well.

Where is the study run from?
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

When is the study starting and how long is it expected to run for?
September 2019 to June 2020

Who is funding the study?
Charité University Medicine Berlin - Working Group Kardiale MRT

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
EKG study

Study information

Scientific Title
Evaluation of the impact of standardised electrode placement positions on gating quality in ultra-high-field cardiovascular magnetic resonance

Study objectives
Different electrode placement positions have an impact on the gating quality in cardiovascular magnetic resonance

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 09/08/2019, ethical board of the Charité University Medicine Berlin Campus Mitte (Charitéplatz 1, 10117 Berlin, Germany; +49 30 450 517 222; ethikkommission@charite.de), ref: EA1/183/19
2. Approved 20/07/2018, ethical board of the Regional Office for Health and Social Affairs Berlin (Turmstraße 21, 10559 Berlin, Germany; +49 30 90229-1232; katja.poetzsch@lageso.berlin.de), ref: Eudamed-Number CIV-18-01-022805, DIMDI Number 00011233 (A)

Study design
Observational study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions

After enrolment participants will be scanned on both clinical as well as the ultra-high-field scanners.
Scan protocol involves one hour of scan time each, during which the ECG-electrodes will be placed on the standardised positions and the ECG will be recorded with the volunteer inside and outside of the scanner for each standardised position and all of the assessed sequences.
In between measurements, the volunteer will be moved outside of the scanner and the ECG-leads will be moved to the next placement position. The trigger accuracy will be evaluated by manually annotating the R-waves in the recorded ECG-trace and determining jitter, performance index and propagation delay of the actual trigger.
After the last scan, the participant will be free to leave and will not be contacted anymore. No follow-up is planned.

Intervention Type
Other

Primary outcome measure
Gating quality assessed by calculating jitter (in ms), performance index and propagation delay (in ms) from evaluating the recorded trigger timepoints against the manually annotated recorded ECG-trace. The annotation will be performed by two independent observers.

Secondary outcome measures
Image quality assessed semiquantitatively by two observers by using a visual rating scale

Overall study start date
01/06/2019

Completion date
10/06/2020

Eligibility

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

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

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

Date of first enrolment
01/09/2019

Date of final enrolment
01/03/2020

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

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Sponsor type
University/education

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité University Medicine Berlin - Working Group Kardiale MRT

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2021

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.

IPD sharing plan summary
Not expected to be made available