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Comparison of new accelerated sequences and standard sequences in cardiac magnetic resonance for the evaluation of cardiac function parameters and mass

Submission date
15/10/2020

Recruitment status
No longer recruiting

Registration date
20/11/2020

Overall study status
Completed

Last Edited
18/07/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The assessment of cardiac (heart) function by cardiac magnetic resonance (CMR) is considered the most precise and reproducible method. A major drawback is the long acquisition time, so researchers want to apply new and faster scan techniques. The aim of this study is to show that compressed sensing sequences can be used to assess heart function in less time. This will facilitate the workflow and increase patient comfort while giving a clinically equivalent assessment of the heart.

Who can participate?
Patients having a CMR scan at the Helios Klinikum Berlin-Buch who are aged 18 or older and do not have an irregular heart rhythm

What does the study involve?
The study compares standard sequences and new faster sequences for the acquisition of CMR images, both obtained during a routine scan.

What are the possible benefits and risks of participating?
None

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?
April 2019 to June 2020

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

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
Nil known

Study information

Scientific Title
Evaluation of Compressed Sensing techniques in MRI for the determination of cardiac function PaRameters compared to Established Segmentation Sequences (ECSPRESS)

Acronym
ECSPRESS

Study objectives
A retrospective study of accelerated cine sequences in comparison to standard cine sequences to show that there are no relevant clinical differences in the quantitative evaluation of left and right ventricular function parameters and mass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submission pending, ethical committee of the Charité Medical Faculty (Charité – Universitätsmedizin Berlin, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany; +49 (0) 30 450 517 222; ethikkommission@charite.de)

Study design
Retrospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Patients with different cardiac diseases with an indication for cardiac MRI

Interventions
The researchers screened the PACS system for CMR scans obtained between May 2019 and July 2020 where new accelerated compressed sensing sequences were used. Cine images from the standard reference method steady-state precession and the compressed sensing techniques are analyzed using CVI42 software (Circle Cardiovascular Imaging Inc., Calgary, Canada) to assess the cardiac morphology. Statistical analyses are performed using IBM SPSS Statistic version 23 (IBM, Armonk, US). The researchers calculate mean values and standard deviation (SD) for demographic parameters, LV and RV function. Images are rated using subjective and objective quality criteria. Differences were considered statistically significant at $p < 0.05$.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Quantitative evaluation of left and right ventricular function parameters and mass (LVEF, LVSV, LVEDV, LVESV, LVM, RVEF, RVSV, RVEDV, RVDSV) measured by compressed sensing sequences and standard cine sequences with cardiac magnetic resonance after the scan

Secondary outcome measures
1. Subjective and objective quality criteria of the cine images measured using standardized criteria after acquisition
2. Time for each acquisition and per slice measured using the DICOM tags after the images are obtained

Overall study start date
01/04/2019

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Indication for cardiac magnetic resonance
2. Age >18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
175

Key exclusion criteria
1. Arrhythmia during the scan
2. No acquired reference cine method

Date of first enrolment
01/05/2019

Date of final enrolment
29/05/2020

Locations

Countries of recruitment
Germany

Study participating centre
Helios Klinikum Berlin-Buch
Schwanebecker Chaussee 50
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Sponsor information

Organisation
Charité University Medicine Berlin

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Sponsor type
University/education

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

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. There will be no additional documents available.

Intention to publish date
01/06/2021

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 the data protection laws in Germany. However, upon request the 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?
Results article		14/07/2022	18/07/2022	Yes	No