# Analysis of heart muscle shape using cardiovascular magnetic resonance imaging

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
04/08/2019		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
27/11/2019	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
26/04/2021	Circulatory System			

## Plain English summary of protocol

Background and study aims

Measuring myocardial (heart muscle) strain is of growing interest in cardiovascular magnetic resonance (CMR) imaging for the detection of subclinical myocardial dysfunction in heart disease. The aim of this study is to assess the age and gender-related reference values of myocardial strain in healthy adults and to evaluate the influence of field strength and postprocessing software.

#### Who can participate?

Data collected in previous studies using CMR were analysed in this study (healthy volunteers aged over 18)

## What does the study involve?

CMR data is analysed to find differences in the results of the analysis using different software and different strengths of scanning devices.

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? January 2018 to July 2019

Who is funding the study?

Charité – Universitätsmedizin Berlin (Charité University Medicine Berlin) (Germany)

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

## Type(s)

Scientific

#### Contact name

Prof Jeanette Schulz-Menger

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# Study information

#### Scientific Title

Quantification of myocardial strain assessed by Cardiovascular Magnetic Resonance feature tracking in healthy subjects – influence of post-processing

#### Study objectives

A retrospective study of strain analysis to establish standards for image acquisition and interpretation and to add further knowledge in this regard by analysing the influence of scanner field strength and analysis software package on age- and gender-related reference values of myocardial strain

#### Ethics approval required

#### Old ethics approval format

## Ethics approval(s)

Approved 04/11/2010 and 17/07/2014, ethical committee of the Charité Medical Faculty (Charité – Universitätsmedizin Berlin, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany; Tel: +49 (0)30 450 517 222; Email: ethikkommission@charite.de), ref: (EA2/077/10), EA1/058/13, DOI, 0.1161/CIRCIMAGING.116.005242

#### Study design

Retrospective proof of concept trial

#### Primary study design

Observational

#### Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

Myocardial strain in healthy volunteers

#### **Interventions**

The researchers screened healthy subjects, who were prospectively examined in former studies. The ethical committee Charite approved all of the studies. All participants were enrolled after informed consent was obtained.

CMR was applied at a 1.5 and 3 T Scanner (Siemens Healthcare, Erlangen, Germany) using a 32 channel surface coil. Cine imaging is performed applying state of the art steady state precession sequences to determine the global cardiac performance in three long axis and short axis.

It is a retrospective trial to evaluate the reference values of myocardial strain applying cardiovascular magnetic resonance (CMR) by analysing the influence of scanner field strength, analysis software package, age- and gender-related factors. This proof of concept trial is intended to extend the indications for CMR.

Subjects were divided into three age groups: group 1 aged < 35 years, group 2 aged 35-55 years and group 3 aged > 55 years

Only volunteers with similar cine protocols were included. Feature tracking analysis was performed using CVI42 software (prototype version 5.3.0, Circle Cardiovascular Imaging Inc., Calgary, Canada). All images were additionally analyzed with TomTec Image Arena (version 1.3.0.91, TomTec Imaging Systems GmbH, Unterschleissheim, Germany).

Statistical analyses were performed using IBM SPSS Statistic version 23 (IBM, Armonk, US). The researchers calculated mean values and standard deviation (SD) for demographic parameters, LV function and strain measurements. Volumes were indexed to body surface area (BSA) and height. Non-parametric Mann-Whitney-U-Test for unpaired samples was used for comparisons of strain parameters between gender, analysis software and field strength. Age-related differences were analyzed using the non-parametric Kruskal-Wallis-Test. Differences were considered statistically significant at p < 0.05.

## Intervention Type

#### Other

#### Primary outcome(s)

- 1. Longitudinal strain assessed in three long-axis views: 4CV, 3CV and 2CV
- 2. Circumferential strain and radial strain assessed short-axis full coverage Measured using CMR at a single timepoint

#### Key secondary outcome(s))

There were no secondary outcome measures

#### Completion date

01/07/2019

# **Eligibility**

#### Key inclusion criteria

- 1. Healthy male and female aged > 18 years
- 2. Preserved left ventricular ejection fraction in echocardiography
- 3. Willingness to undergo CMR
- 4. Willingness and ability to follow directions and complete all study procedures as specified in the protocol

#### Participant type(s)

Healthy volunteer

# Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Total final enrolment

67

#### Key exclusion criteria

- 1. Any known cardiovascular risk factor
- 2. History of cardiac disease
- 3. Impaired LV ejection fraction (LVEF) (< 55%)
- 4. Pathologic findings in CMR
- 5. Incomplete CMR data for feature tracking analysis (less than three long axis and three short axis views) led to exclusion

#### Date of first enrolment

01/01/2013

# Date of final enrolment 08/11/2017

# Locations

Countries of recruitment

Germany

13125

Study participating centre
Charité University Medicine Berlin
Working Group Kardiale MRT
Lindenberger Weg 80
Berlin
Germany

# Sponsor information

## Organisation

Charité University Medicine Berlin

#### **ROR**

https://ror.org/001w7jn25

# Funder(s)

#### Funder type

University/education

#### **Funder Name**

Charité – Universitätsmedizin Berlin

# **Results and Publications**

## 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 reasons of 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?
Results article		01/06/2021	26/04/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes