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Cardiac magnetic resonance shows a different heart motion in healthy obese compared to normal-weight volunteers

Submission date 26/04/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/06/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/06/2022	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a major public health issue with nearly a third of the world population being classified as overweight or obese and has numerous adverse effects on cardiovascular (CV) health. Obese persons without CV disease might have already early manifestations of cardiac dysfunction without symptoms. The aim of our study is to explore heart motion and structure in healthy obese persons and the influence of a 6-month of reduced-carbohydrate (R-C) and reduced-fat (R-F) low calorie diet on heart motion and structure.

Who can participate?
Data collected during an earlier study (2007 - 2011) was used in this study. No new participants were included in the study.

What does the study involve?
Data were retrieved and analysed to explore heart motion and structure in healthy obese persons and the influence of a 6-month of reduced-carbohydrate and reduced-fat low calorie diet on heart motion and structure.

What are the possible benefits and risks of participating?
None

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?
October 2019 to April 2021

Who is funding the study?
Investigator initiated and funded

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
Myocardial deformation and cardiac remodeling is influenced by obesity - assessment of myocardial strain by CMR feature tracking in healthy obese

Acronym
B-SMART (FT) CMR

Study objectives
The study has two aims. Firstly, the researchers want to screen for cardiac remodeling in healthy obese persons by comparing them to healthy normal-weight persons. Secondly, they want to explore the influence of a 6-month of reduced-carbohydrate (R-C) and reduced-fat (R-F) hypocaloric diet on cardiac remodeling in healthy obese persons.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/05/2004, 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), ref: AA3/04/24

Study design
Retrospective analysis

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Cardiac remodeling

Interventions
The analysis is part of the B-SMART Study (Berlin Study of Metabolomics in Adiposity and its Role for Successful Therapy) (ClinicalTrials.gov Identifier: NCT00956566). This prospective randomized study (April 2007 – December 2011) compared the effects of a 6-month hypocaloric diet with either reduced-carbohydrate (R-C) or reduced-fat (R-F) content on body weight reduction and metabolic and cardiovascular variables in 170 obese healthy women and men. 110 subjects completed the intervention phase and of those CMR imaging at 1.5T (Sonata and Avanto, Siemens Medical Solutions AG, Erlangen, Germany) at baseline and after diet could be obtained in 95 subjects. Of those, five subjects were excluded due to poor image quality at baseline or after diet, leaving a final intervention study cohort of 90 individuals, who were retrospectively analyzed using CMR feature tracking. Data was compared to 34 healthy non-obese volunteers (BMI <25 kg/m²). Post-processing was performed applying CVI42 (Version 4.1.2, Circle Cardiovascular Imaging Inc). Left ventricular (LV), right ventricular (RV), left atrial (LA), right atrial (RA) volume assessment was based on steady-state free precession (SSFP) cine images. Circumferential strain (CS) and radial strain (RS) were analyzed using short-axis views (SAX) and longitudinal strain (LS) using three long-axis (LAX) views. Strain was analyzed for each slide and each segment.

Intervention Type
Procedure/Surgery

Primary outcome measure

Myocardial deformation is measured by applying cardiac magnetic resonance feature tracking software (CVI42 (Version 4.1.2, Circle Cardiovascular Imaging Inc.)) at baseline and after 6 months

Secondary outcome measures
Left atrial volume, right atrial volume, right ventricular volume, and left ventricular mass/volume ratio are measured at baseline and after 6 months. Units for volume are ml. Unit for left ventricular mass/volume ratio is g/ml. All secondary measures are collected by cardiac magnetic resonance data and are quantified by applying (CVI42 (Version 4.1.2, Circle Cardiovascular Imaging Inc.))

Overall study start date
01/10/2019

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Age >18 and <60 years
2. BMI >27 kg/m²
3. No medication except contraceptives or L-thyroxine
4. Discontinuation of a chronic medication must be medically justifiable because improvement in the condition for which the medication is being taken can be expected through weight loss

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
124

Total final enrolment
170

Key exclusion criteria
1. Pregnancy/lactation
2. Diseases or functional disorders that, in the opinion of the investigator, preclude participation in a clinical trial
3. Manifest endocrinological or metabolic diseases requiring treatment (diabetes mellitus, hypo- and hyperthyroidism, Cushing's syndrome, M. Cushing syndrome, Cushing's disease); normal TSH with L-thyroxine use is acceptable

4. Manifest cardiovascular diseases requiring treatment (hypertension like RR > 160/95 mmHg or > two medications; coronary artery disease or previous myocardial infarction; cerebral ischemia or apoplexy; clinically significant diseases of the blood vessels (stenoses of the vessels supplying the brain; renal artery stenoses, pAVK)
5. Diseases of the kidney, liver, or gastrointestinal tract that require treatment and intestinal tract that require chronic medication
6. Significant neurological or psychiatric disorders (depression, epilepsy, schizophrenia, bulimia nervosa)
7. History of bariatric surgery
8. Known or proven abuse of medication, drugs or alcohol
9. Tumor diseases; postoperative phase
10. Acute and chronic infections
11. Incapacity or circumstances that do not allow the patient to fully understand the nature, meaning, and implications of this study
12. Metal implants and other contraindications by performing MRI (body weight > 130 kg)

Date of first enrolment
01/04/2007

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Germany

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

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

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
Results of the study will be published in a high ranking peer-reviewed journal.

Intention to publish date
31/12/2021

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 confidentiality.

IPD sharing plan summary
Not expected to be made available