Comparison of Left and Right Ventricular Geometry and Functional Parameters in Chronic Fatigue Syndrome Patients versus Age- and Sex- Matched Healthy Controls Assessed by Cardiovascular Magnetic Resonance Imaging.

Published: 18-10-2010
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Objective: To establish LV and RV geometry and function, and tissue characterization in age- and gender-matched healthy controls (serving as reference group for the CFS patients) by using own CE-CMR imaging.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON39100

Source
ToetsingOnline

Brief title
Normal values of Left and Right ventricular dimensions by CMR imaging

Condition

- Heart failures

Synonym
chamber function, heart function

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Keyword: cardiovascular magnetic resonance, dimensions, normal values, right/left ventricle

Outcome measures

Primary outcome

The main study parameters will be LV and RV geometry and function (i.e., LV and RV end-diastolic volume, end-systolic volume, end-diastolic wall mass, wall motion score and ejection fraction) and tissue characterization of the myocardium, to assess presence and extent of CE.

Secondary outcome

To assess the level of activity* in the healthy female volunteers in order to correspond with the physically inactive CFS population and to assess if small expected differences in LV/RV geometry, function and tissue characterization in the female healthy subgroup can be explained by individual level of activity.

* The level of activity in the individual healthy volunteers is quantitatively determined by (1) using a validated questionnaire and (2) completing a bicycle exercise test.

Study description

Background summary

Rationale: Cardiovascular magnetic resonance (CMR) imaging is an accurate and reproducible tool for the estimation of both left ventricular (LV) and right ventricular (RV) geometry and function. CMR has also the unique capability to obtain tissue characterization (i.e., presence and extent of scar/fibrosis) of the myocardium after intravenous injection of a contrast agent. However, data on reference values of RV and LV geometry and function, and tissue characterization are scarce, and differences among age- and gender- matched subgroups have been observed. Further, reference values with our own CMR imaging modality have not been obtained.
Recently, we examined a small female chronic fatigue syndrome population (n=12, age range 20-60) with contrast enhancement (CE)-CMR imaging to assess cardiac involvement. We found relatively lower dimensions and a mildly reduced function of the LV in comparison with age and gender-matched reference values. On the CE-images, presence of myocardial fibrosis in some CFS patients was seen.
To improve the reliability of these data, it would be ideal to asses blinded, at random parameters of LV and RV geometry and function and tissue characterization in chronic fatigue syndrome patients as well as in age- and sex- matched controls by using own CMR imaging modality.

Study objective

Objective: To establish LV and RV geometry and function, and tissue characterization in age-and gender-matched healthy controls (serving as reference group for the CFS patients) by using own CE-CMR imaging.

Study design

Study design:The Normal-CMR study is a single center case control study

Study burden and risks

Completing the questionnaire and bicycle exercise testing is not associated with a risk.

During the CMR, the healthy volunteers will receive intravenously contrast in order to perform myocardial tissue characterization. There is a hypothetical risk of nephrogenic systemic fibrosis associated with gadolinium-based contrast used in CMR. Nephrogenic systemic fibrosis occurs exclusively in patients with kidney failure and as for this study only healthy volunteers are selected, it is highly unlikely to occur. The incidence of systemic nephrogenic sclerosis due to the contrast used in this study (see appendix B) is 0% according to the manufacturer. CMR-scanning can be unpleasant to people with claustrophobia.

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

Healthy female volunteers, age range 20-60 years.
Able to provide informed consent.

Exclusion criteria

Previous cardiovascular disease
known diseases with cardiac involvement
Unwillingness to use or contra-indications for contrast agents
Age < 20 or > 60 years
Pregnancy
Breast feeding

Kidney dysfunction
Body mass index > 30
Claustrophobia or other exclusion criteria for MRI such as implanted metal materials

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2010
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	18-10-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	01-11-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	19-11-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL33018.044.10