Energetics in hypertrophic cardiomyopathy: translation between PET, MRI and cardiac myofilament function

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Ethical review	Approved WMO
Status	Completed
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON44786

Source
ToetsingOnline

Brief title
'ENGINE'-study

Condition

- Myocardial disorders

Synonym
hypertrophy, thickening of the heart muscle

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: oa. FP7-grant;toegekend aan J. van der Velden (afd. fysiologie).

Intervention

Keyword: Energetics, HCM, myofilaments, PET

Outcome measures

Primary outcome

Correlation of energetic properties of the HOCM-heart (in vivo assessment with

PET and MRI) with it*s in vitro (myofilamental) efficiency of contraction.

Secondary outcome

- Comparison of energymetabolism (in vivo, in vitro) between HCM, aortic valve

stenosis and non-hypertrophic carriers.

- Histological determination of interstitial fibrosis and it*s relation to

septal (regional) contraction using CMR tagging.

- Peak strain values compared to contractile velocities of myofilaments.

- Relation between existence of myocardial disarray and the extent of

remodelling.

Study description

Background summary

Disturbed energetic homeostasis of the myocardium is thought to play a role in the pathogenesis of HCM related hypertrophy.

Study objective

Within this project we aim to determine the energetic conditions that underlie the transition to hypertrophy of the HOCM heart. A prospective comparison will be made between results of PET, MRI and function of cardiac myofilaments (in

vitro).
Also, energetic myocardial homeostasis will be compared between HOCM patients and patients with aortic valve stenosis (having concentric hypertrophy) and carriers (without left ventricular hypertrophy), all selected for surgery (except carriers), since we expect metabolic differences in HCM-related hypertrophy, concentric hypertrophy and normal non- overloaded myocardium.

Study design

Study design: prospective, open, multicenter

Study burden and risks

Patients will undergo a echocardiography, PET/MRI- investigations and a exercisetest in supine position for a maximum of 1,5 hour per investigation. To minimize the burden of travelling, both procedures will be carried out on the same day. For intravenous administration of the contrast-agent Gadolinium-DTPA (Dotarem ©), a venflon will be inserted in the vena brachialis. Patients with renal failure (glomerular filtration rate (GFR) < 30 ml/min) will be excluded to avoid development of Gadolinium-DTPA induced nephrogenic systhemic fibrosis (NSF). Obtainment of (single) LV septal biopsies in AVS-patients is regarded safe, due to extensive experience of operators, clear visibility of the interventricular septum after thoracotomy, and the small size of (single) biopsies (2mm x 200µm x 0.15mm). As a result, the risk for conduction abnormalities is negligible small. For comparison, obtainment of endomyocardial biopsies during catheterisation has a low complication rate, while multiple (larger) biopsies are taken without clear visibility

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

HOCM-patients scheduled for classic myectomy and eligible for CMR-and PET imaging. Indication for myectomy was based on a significant LV outflow tract (LVOT) pressure gradient >=30 mmHg at rest or provoked as documented by echocardiography and symptoms, despite optimal medical treatment.
Aortic valve stenosis patients selected to undergo valve surgery, according to the ESC-guidelines on the management of valvular heart disease.
Non-hypertrophic carriers (NHC) eligible for CMR- and PET imaging;Ref. Vahanian A et al. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J. 2007 Jan;28(2):230-68. ;Protocol page 11-12

Exclusion criteria

Any absolute or relative contra-indication for CMR imaging (i.e. pacemaker and claustrophobia) or failure to give informed consent. Severely impaired renal function with a glomerular filtration rate (GFR) <30 ml/min.
Protocol page 11-12

Study design

Design

Study type:	Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-06-2011
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	20-09-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	29-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL29526.029.09