Identifying novel biomarkers in left ventricular hypertrophy patients

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Our first objective is obtaining hypertrophic myocardial tissue for identifying novel biomarker, indicative and predictive for the severity of cardiac hypertrophy. Our second objective is validation of biomarkers detected in previous studies.

Ethical review	Not approved
Status	Will not start
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON32278

Source
ToetsingOnline

Brief title
Biomarkers in left ventricular hypertrophy

Condition

- Myocardial disorders

Synonym
biomarkers, heart hypertrophy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomarkers, left ventricular hypertrophy, proteins

Outcome measures

Primary outcome

identifying proteins involved in myocardial hypertrophy

Secondary outcome

validation of biomarkers in hypertrophic myocardial tissue

Study description

Background summary

The presence of left ventricular hypertrophy is clinically important since it is a strong independent risk predictor of heart failure1. Left ventricular hypertrophy (LVH) is also associated with an increased risk for developing ventricular and atrial arrhythmias, coronary artery disease (myocardial infarction) and cardiovascular death.Several studies have already determined the possibility of left ventricular mass reduction, using different blood pressure lowering therapeutic agents as ACE-inhibitors, AT-2 inhibitors and beta-blocking therapy, which also improves clinical outcome. LVH development is associated with the induction of altered genetic programming. Animal studies have researched if left ventricular function improves by inhibiting LVH, using the knowledge of the different hypertrophy pathways. What stands out: decreasing left ventricular hypertrophy results in improved left ventricular function and thus clinical outcome. ECG-criteria and 2-D echocardiography is most often used to detect LVH. Although the accuracy of 2-D echocardiography is 0.905, the standard error of the estimate is 38.5 g. This means, not only that ultrasound can miss LVH, but also that small differences in left ventricular (LV) mass, caused by treatment can be left undetected. Biomarkers for hypertrophy could possibly determine therapeutic effects of different antihypertensive agents more reliably. In addition, in a rat model it is found that intervening in LVH to improve LV-function, works more efficiently when intervening early in disease. Biomarkers for hypertrophy could then possibly detect LVH much earlier than the now used ECG-criteria and echocardiography and thus leading to improved outcome. In addition, biomarkers could be used to predict the outcome post surgery as in some pts the heart is beyond repair.

Study objective

Our first objective is obtaining hypertrophic myocardial tissue for identifying novel biomarker, indicative and predictive for the severity of cardiac hypertrophy. Our second objective is validation of biomarkers detected in previous studies.

Study design

This study is designed as an monocenter observational study. Patients planned for aortic valve surgery will be approached for participation. During surgery myocardial tissue is obtained. One half of tissue will be snap frozen in liquid nitrogen and stored at -80°C for further analysis. The other half of myocardial tissue will be placed in NaCl 0.9%, and taken to the experimental cardiology laboratory for protein analysis and storage. For further description of tissue analysis, see Protocol page 2.

Study burden and risks

Patients are asked to undergo myocardial biopsy during their already planned surgery. According to the thoracic surgeons this does not lead to any additional risk for the patient. Patients will not be contacted again after their surgery. We think the risk and burden for the patients are thus very small and since we*re gaining a huge amount of scientific knowledge considering left ventricular hypertrophy and probably a new and easy diagnostic tool we think this is justified.

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

Patients are included in this study when planned for surgical aortic valve replacement for severe aortic valve stenosis. Signs of left ventricular hypertrophy have to be present either on ECG, echocardiography or MRI. None of the exclusion criteria are met. Written informed consent is obtained.

Exclusion criteria

Patients with concomitant heart disease: previous myocardial infarction, endocarditis. Patients younger than 18 years of age are also excluded from participation in this study. Patients who have a syndromic or genetic diagnosis, for example, Marfan*s disease, trisomy 21, and Turner*s syndrome

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:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	25-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL22028.041.08