Prevalence of virus persistence and inflammation in heart failure

Published: 27-07-2007
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Quantifying the viral persistence and related inflammation in normal hearts versus idiopathic, ischemic, hypertensive and familial cardiomyopathie.

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

Summary

ID

NL-OMON31075

Source
ToetsingOnline

Brief title
Viruses in the heart

Condition

- Heart failures

Synonym
heart failure; cardiac dysfunction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Heart failure, Inflammation, Viruses

Outcome measures

Primary outcome

Comparing the degree of viral presence between the different groups using PCR

analysis of the biopsies.

Secondary outcome

Additional analysis of the type/degree of inflammation in the myocardium using

histological and immunohistological examination.

Study description

Background summary

Viral persistence is increasingly being recognized as an important factor in acute and chronic heart failure. The present study is to further investigate the prevalence of virus persistence and related inflammation in idiopathic cardiomyopathy (CMP), heart failure of unknown origin. We will investigate whether viral presence may aggravate heart failure caused by hypertensive, ischemic, valvular or familial CMP.

Study objective

Quantifying the viral persistence and related inflammation in normal hearts versus idiopathic, ischemic, hypertensive and familial cardiomyopathie.

Study design

This is a cross-sectional analysis of virus presence and viral load between the different groups.
Cardiac biopsies are collected and analysed from 40 patients within each group (160 total) either during planned cardiao-thoracic surgery or during the coronary angiogram including diagnostic biopsies as routine diagnostic work-up for idiopathic cardiomyopathie.
Furthermore additional blood (30ml) will be collected for future research in the line of this project.

Study burden and risks

Three transmural biopsies will be obtained during elective cardiac surgery for coronary or valvular CMP. This is a very safe procedure, with a very low risk (<1 %) of peri-operative complications. Arrhythmias, perforation and post-operative bleeding is prevented by placing a stitch at the place of biopsy taking. Post-operative complications with this procedure has never been described.
Seven diagnostic endomyocardial right ventricular biopsies are taken in patients with idiopathic dilated cardiomyopathy, as part of a routine diagnostic work-up. Here, patients with a prior history of arrhythmias may have the rhythm exacerbated by endocardial irritation. Pericardial bleeding as a consequence of right ventricular perforation occurs in about 0.5%, requiring pericardial drainage in 50%.
The amount of extra blood taken is minor (30ml) that no complications are expected.

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 with idiopathic heartfailure undergoing routine analysis (including cardiac biopsies).
Patients with or without heartfailure undergoing elective cardio-thoracic surgery.

Exclusion criteria

Emergency cardiothoracic surgery
Pregnancy or lactation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	27-07-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	07-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL17724.068.07