Non-invasive Risk Stratification for Ventricular Arrhythmias in Ischaemic and non-ischaemic Cardiomyopathy

Published: 29-10-2008
Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON38278

Source
ToetsingOnline

Brief title
No RIsC-study

Condition

- Cardiac arrhythmias

Synonym
cardiac arrhythmias, ventricular arrhythmias in cardiomyopathy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: CTMM

Intervention

Keyword: Cardiomyopathie, ICD, imaging, ventricular arrhythmia

Outcome measures

Primary outcome

Excitability of LV for arrhythmias, ventricular arrhythmias

Secondary outcome

N/A

Study description

Background summary

The number of patients with ischaemic or dilated cardiomyopathy (CMP) is steadily increasing in western civilized countries, among others due to the advances in pharmacological and revascularization therapies in coronary artery disease. Sudden cardiac death due to ventricular arrhythmias is a feared complication in these patients. The introduction of the implantable cardioverter defibrillator (ICD) has had a major impact in the treatment of CMP with a significant reduction in mortality. However, only 35% of treated patients are faced with an appropriate discharge for the occurrence of life-threatening ventricular arrhythmias during a follow-up period of three years. Although the exact characteristics of the myocardial substrate for ventricular arrhythmias in ischaemic heart disease remains incompletely understood, several predictors have been identified. Recently, cardiac magnetic resonance imaging (CMR) with the contrast agent gadolinium has emerged as an imaging tool that allows accurate quantification of scar tissue. Furthermore, the MOLLI sequence allows diffuse assesment of fibrosis. It was demonstrated that size of fibrosis and heterogeneity of scar tissue measured by CMR are better predictors of inducible ventricular tachycardia (VT) than LVEF in patients with CMP. Besides the aforementioned, sympathetic activity and cardiac denervation seem to contribute to the susceptibility of arrhythmias. Animal experiments have subsequently suggested that the area of viable and perfused but denervated myocardium is highly sensitive to sympathetic stimuli, which may trigger ventricular arrhythmias. Furthermore, innervation defects have been described in patients with dilated cardiomyopathy. Recently, tracers have been introduced for scintigraphic mapping of presynaptic sympathetic innervation. Scarce clinical data of several studies using the tracers confirm the hypothesis that innervation imaging may be useful in the risk stratification

process for ventricular arrhythmias in CMP patients. Given the increasing importance of this topic in the current era of increasing prevalence of CMP, ICD implantations, and expanding health care costs, the aforementioned potential predictors for sudden death due to ventricular arrhythmias in CMP patients warrant further investigation.

Study objective

The present study is designed to test the hypothesis that new imaging modalities like PET with the use of HED and contrast enhanced CMR to quantify fibrosis size and heterogeneity of scar tissue can give a further risk stratification for ventricular arrhythmias in patients with ischaemic or dilated cardiomyopathy and a LVEF < 35%.

Study design

BASELINE PARAMETERS:
- Standard physical examination
- ECG
- Minnesota living with heart failure questionnaire
- lab test (among other NT-proBNP and CRP)
- Microvolt T wave alternans testing

Noninvasive imaging protocol:

Echocardiography
- Standard RV and LV evaluation
- Real time 3D echo dataset acquisition

MRI
- RV and LV volumes and function
- Delayed contrast enhancement to detect RV and LV scarring.

PET
- Assessment of myocardial perfusion using H215O
- Assessment of innervation using 11C-HED

Invasive measurements:

Electrophysiological testing during ICD-implantation
- Assessment of excitability of VT/VF

During the same session as the electrophysiological testing the patients will have implanted an ICD. And after the implantation patients will be subjected to periodical out-house screening of the device for arrhythmias for a period of at least three years. Both the electrophysiological data (excitable VT/VF) as well

as the follow-up occurrence of arrhythmias will be related to the baseline imaging data in an effort to identify the most powerful predictors of arrhythmias in our study population.

Study burden and risks

Participants will be exposed to a total of 3.4 mSv for the PET study protocol. This amount is comparable to less than two times the annually background radiation.
The adenosine injected during the PET study protocol can induce headache and a flush. In some cases chestpain can occur. All side-effects disappear quickly after stopping the adenosine infusion (about one minute).

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

EF < 35%
ischaemic or dilated cardiomyopathy
scheduled for ICD implantation
sinus rhythm

Exclusion criteria

No informed consent
Claustrophobia

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):	31-03-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	25-09-2012
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	NL19680.029.08

Study results

Date completed:	03-04-2018
Actual enrolment:	80