Improving risk stratification for infarction related sudden cardiac death by combining cardiac magnetic resonance imaging, electrocardiographic imaging and epicardial mapping.

Published: 10-06-2015
Last updated: 19-04-2024

The aim of this study is to discover a new set of parameters to define the electropathological substrate by integrating cardiac magnetic resonance imaging (CMR) and non-invasive electrocardiographic imaging (ECGI) characteristics. In the future,...

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

Summary

ID

NL-OMON42753

Source
ToetsingOnline

Brief title
Combining CMR, ECGI and epicardial mapping

Condition

- Cardiac arrhythmias

Synonym
Sudden cardiac death, ventricular arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Onderzoeksbudget Haga Hartcentrum

Intervention

Keyword: CMR, non-invasive electrocardiographic imaging, risk stratification, sudden cardiac death

Outcome measures

Primary outcome

The primary study parameters include:

- 3D electrical activation maps using epicardial mapping and ECGI.

- The electrocardiographic characteristics (voltage amplitude, voltage

duration, conduction velocity, fractionation) of the different tissue types

(e.g. normal myocardium and scar).

- The correlation between the electrocardiographic characteristics measured

using epicardial mapping and ECGI.

- 3D myocardial scar maps.

- CMR characteristics of the different tissue types (e.g. normal myocardium and

scar).

- The correlation between the 3D electrical activation maps obtained using ECGI

with the 3D CMR myocardial scar maps.

Secondary outcome

Secondary study parameters include e.g. individual evaluation of deaths and

hospitalizations.

Study description

Background summary

Patients with a history of myocardial infarction (MI) are at increased risk of sudden cardiac death (SCD). An implantable cardiac defibrillator (ICD) is a device designed for acute treatment of life threatening ventricular tachyarrhythmias causing SCD.
Current guideline recommendations focused on ICD implantation for the prevention of infarction related SCD are primarily based on a reduced left ventricular ejection fraction. However, the majority of SCD cases occur in patients with preserved or moderately reduced LVEF. In addition, relatively few patients with a reduced LVEF ever experience a life-threatening arrhythmic event. Consequently, current approaches for risk stratification for myocardial infarction related SCD remain insufficient. In addition, inappropriate ICD therapy (ICD therapy for atrial tachyarrhythmias instead of ventricular tachyarrhythmias) occurs on a regular basis and is a large burden for patients with an ICD. It is therefore of importance to improve risk stratification and consequently patient selection for ICD therapy.

Study objective

The aim of this study is to discover a new set of parameters to define the electropathological substrate by integrating cardiac magnetic resonance imaging (CMR) and non-invasive electrocardiographic imaging (ECGI) characteristics. In the future, these new characteristics may contribute to improve risk stratification for the occurrence of infarction related SCD and consequently improve patient selection for ICD implantation.

Study design

This study will consist of a multi-center prognostic, follow-up study which will be performed at Haga Teaching Hospital and Erasmus Medical Center. A total of 330 CABG patients will undergo cardiac MRI and ECGI prior to surgery. Epicardial mapping will be performed during surgery, immediately prior to commencement to extracorporeal circulation. 3-6 Months after CABG, patients will undergo a second CMR and ECGI to assess changes in the electrical and tissue characteristics as a consequence of the CABG. In addition, a total of 300 patients with prior myocardial infarction scheduled for ICD implantation will undergo cardiac MRI and ECGI prior to implantation. Total study duration is maximal three years with a minimum follow-up of one year and a maximum follow-up of three years.

Study burden and risks

An MRI scan is a prerequisite for the BSPM and to asses ICD indications. Although non-invasive, this diagnostic modality can cause nausea, headache or general discomfort, especially in subjects suffering from claustrophobia. ECGI uses 256 or 512-channel ECG recordings. ECG electrodes can cause skin irritation and allergic reactions. Epicardial mapping will prolong the surgical procedure by 10 minutes on average. There are no additional risks associated with the mapping procedures.

Contacts

Public
HagaZiekenhuis

Leyweg 275
Den Haag 2545CH
NL
Scientific
HagaZiekenhuis

Leyweg 275
Den Haag 2545CH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

CABG group: Patients scheduled for elective coronary artery bypass grafting.
a.Patients without a history of myocardial infarction and ventricular tachyarrhythmias (No-infarct group).

b. Patients with a previous myocardial infarction, but no history of ventricular tachyarrhythmias (No-VT group).
c. Patients with a previous myocardial infarction and a history of ventricular tachyarrhythmias (VT group). ;ICD group: Patients with a prior myocardial infarction, scheduled for ICD implantation.

Exclusion criteria

- Any contraindication for MRI.
- Pregnant women, or women of child bearing potential and who are not on a reliable form of birth control

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):	09-11-2015
Enrollment:	630
Type:	Actual

Ethics review

Approved WMO

Date:	10-06-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL53035.098.15

Study results

Date completed:	21-02-2017
Actual enrolment:	11