Mapping and ablation of the functional substrate in ischemic heart disease with mini- micro- and conventional electrodes

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The objectives of this study are: 1) to assess the feasibility, accuracy and efficacy of simultaneous, conventional and micro-electrode mapping using the QDOT catheter to delineate and ablate the functional substrate of post-MI VT compared to…

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

Summary

ID

NL-OMON50104

Source
ToetsingOnline

Brief title
Multielectrode functional substrate mapping

Condition

- Cardiac arrhythmias

Synonym
Heart rhythm disorder, Ventricular arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: Ministerie van OC&W,Biosense Webster

Intervention

Keyword: Functional substrate, Multielectrode mapping, Myocardial infarction, Ventricular tachycardia

Outcome measures

Primary outcome

Mapping accuracy of the micro-electrodes of the QDOT catheter in re-

identifying evoked delayed potentials (EDP) detected by the Pentaray/Octrell

catheter and confirmation of EDP elimination.

Secondary outcome

- Mapping time using the QDOT catheter to delineate EDP compared to functional

substrate delineation with the Pentaray/Octrell catheter

- Wave-front and pacing-rate (coupling interval) dependency of QDOT micro/conv.

vs. Pentaray/Octrell for voltage mapping (=scar delineation) and functional

substrate mapping (=EDP identification)

- VT recurrence

- All course mortality

Study description

Background summary

A three-step approach is currently applied for functional substrate mapping and ablation of ventricular tachycardia after myocardial infarction. First, substrate mapping with a multipolar catheter with small and narrow-spaced electrodes followed by ablation with a single-tip conventional catheter and re-mapping with the multielectrode catheter. The QDOT ablation catheter incorporates three microelectrodes in addition to the conventional bipolar electrodes which may allow for identification of the functional substrate and ablation with a single catheter.

Study objective

The objectives of this study are: 1) to assess the feasibility, accuracy and efficacy of simultaneous, conventional and micro-electrode mapping using the QDOT catheter to delineate and ablate the functional substrate of post-MI VT compared to multielectrode mapping with the Pentaray/Octrell catheter for different infarct subtypes (large transmural to subendocardial re-perfused MI), 2) to evaluate the potential benefit of combined mini - micro and conventional electrode mapping for substrate delineation and ablation endpoint determination, and 3) to establish a patient-tailored workflow for optimal substrate mapping.

Study design

This will be a multi-center prospective observational study.

Study burden and risks

The burden associated with taking part in the study is a lengthened procedure time (max. 20 minutes).
Patients in the evaluated group may benefit from participating in this study. As with the QDOTcatheter operators may be able to re-confirm the functional VT substrate before RF delivery at the exact same site, this may result in improved substrate elimination and outcome. If the accuracy of the QDOT catheter to detect evoked delayed potentials results to be similar than with the Pentaray/Octrell catheter, and if with the QDOT catheter acute lesion formation can be assessed, future patients might benefit from a shorter procedure (no remapping required).

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

- Sustained within 6 months before enrolment.
- Accepted for catheter ablation of VT.
- Prior MI. The diagnosis of MI will be based on the presence of wall motion abnormalities, non-reversible perfusion defects and/or subendocardial or transmural late gadolinium enhancement areas in the perfusion territory of a significant stenotic coronary artery (>75 %).

Exclusion criteria

- Age < 18 years
- Inadequate patient competence
- Pregnancy
- Presence of any of the following conditions:
o Non-ischemic left-dominant cardiomyopathy
o Right dominant cardiomyopathy
o Hypertrophic cardiomyopathy
o LV non-compaction cardiomyopathy
o Restrictive cardiomyopathy
o (Sub)acute myocarditis
o Cardiac sarcoidosis
o Chagas disease
o Tachycardia-induced cardiomyopathy
o Primary significant valve disease
o Congenital heart disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2021
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	27-01-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-10-2024
Application type:	Amendment
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	NL74386.058.20