Ventricular Tachycardia in Ischemic Cardiomyopathy; a Combined Endo-Epicardial Ablation Within the First procedure Versus a Stepwise Approach a randomized controlled trial

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To show superiority of a combined endo/epicardial approach compared to a stepwise approach in the ablation of ventricular tachycardia in a population with ischemic cardiomyopathy on VT recurrence.

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

Summary

ID

NL-OMON53074

Source
ToetsingOnline

Brief title
Epilogue

Condition

- Cardiac arrhythmias

Synonym
ventricular tachycardia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Biotronik,zie hieronder

Intervention

Keyword: epicardial ablation, ischemic cardiomyopathy, ventricular tachycardia

Outcome measures

Primary outcome

The main study endpoint is the difference in recurrences of ventricular

tachycardia on follow-up - clinical or on ICD interrogation - between the two

ablation groups

Secondary outcome

Procedure success and safety.

Study description

Background summary

Nowadays VT ablation in structural heart disease is performed primarily by early referral; while at the same time we still struggle with the limited longterm ablation success of endocardial VT ablation. An underestimated number of VTs from ischemic substrate have an epicardial exit. However, one cannot accurately predict who is in need of epicardial ablation. We hypothesise endo/epicardial substrate homogenization in a first approach to be superior to endocardial substrate homogenization alone, in terms of recurrence on follow-up.

Study objective

To show superiority of a combined endo/epicardial approach compared to a stepwise approach in the ablation of ventricular tachycardia in a population with ischemic cardiomyopathy on VT recurrence.

Study design

Multicenter prospective open randomized controlled trial.

Intervention

Combined endo/epicardial substrate homogenization in a first approach

Study burden and risks

There will be few additional discomforts related to the study for patients participating in this study. All treatment arms are part of current treatment practice. Risk associated with epicardial VT ablation is acceptably low and physical discomfort associated with pericardial access is generally mild and self-limiting. There is a low risk of tamponade and perforation of surrounding tissue. Subjects participating in the study will possibly have less recurrence of VT and subsequently a lower incidence of ICD therapy. There will be no additional burden on follow-up, where the frequency of ICD interrogation in this population is as clinically indicated.

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

1. clinical indication for ablation of a monomorphic ventricular tachycardia referred to one of the participating ablation centers
2. history of ischemic heart disease
3. ICD carrier or ICD implantation planned after the ablation
4. informed written consent

Exclusion criteria

1. current unstable angina
2. AMI < 30 days or in case of incessant VT < 14 days
3. absence of visualisation of the coronary anatomy (coronary angiogram /CT-angiogram)
4. significant coronary stenosis approachable for intervention
5. presence of a mobile left ventricle thrombus
5. previous pericarditis
6. presence of mitral/aortic mechanical valves prosthesis; previous coronary artery bypass graft; any other thoracic surgery that could cause pericardial adhesions
7. contra-indication for general anaesthesia
8. age below 18 years

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-07-2015
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	17-02-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48168.078.14