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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22465

Source
Nationaal Trial Register

Brief title
epilogue

Health condition

scar related ventricular tachycardia

dutch: ventrikel tachycardie

Sponsors and support

Primary sponsor: ErasmusMC
Source(s) of monetary or material Support: medtronic

Intervention

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

The secondary endpoints are procedure success and safety

Study description

Background summary

The objective of this study is 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.

Study population: All patients above 18 years with an ischemic cardiomyopathy being referred for a ventricular tachycardia ablation.

Study objective

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 design

2 years follow-up

Intervention

One group undergoes endo/epicardial ablation and the other group has endocardial ablation only as a first approach.

Contacts

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Eligibility criteria

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 as defined by current european guidelines

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 and clinically relevant for intervention

5. presence of a mobile left ventricle thrombus seen on (contrast) echocardiograpy or MRI

6. previous pericarditis

7. presence of mitral/aortic mechanical valves prosthesis; previous coronary artery bypass graft; any other thoracic surgery that could cause pericardial adhesions

8. previous thoracic radiation therapy

9. contra-indication for general anaesthesia

10. age below 18 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2015
Enrollment:	125
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-01-2015
Application type:	First submission

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
NTR-new	NL4989

Register	ID
NTR-old	NTR5136
Other	MEC : 2014-248

Study results