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 followup - 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 abl	lation of a	monomorphic	ventricular	tachycardia	referred t	o one	of
th	e participating ablation c	enters						

- 2. history of ischemic heart disease
- 3. ICD carrier or ICD implantation planned after the ablation
- 4. informed written consent

Exclusion criteria

Study design
10. age below 18 years
9. contra-indication for general anaesthesia
8. previous thoracic radiation therapy
7. presence of mitral/aortic mechanical valves prosthesis; previous coronary artery bypass graft; any other thoracic surgery that could cause pericardial adhesions
6. previous pericarditis
5. presence of a mobile left ventricle thrombus seen on (contrast) echocardiograpy or MRI
4. significant coronary stenosis approachable and clinically relevant for intervention
3. absence of visualisation of the coronary anatomy (coronary angiogram /CT-angiogram)
2. AMI < 30 days or in case of incessant VT < 14 days
1. current unstable angina as defined by current european guidelines

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

NTR-old NTR5136

Other MEC : 2014-248

ID

Study results