

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

Gepubliceerd: 20-01-2015 Laatst bijgewerkt: 18-08-2022

We hypothesize endo/epicardial substrate homogenization in a first approach to be superior to endocardial substrate homogenization alone, in terms of recurrence on follow-up.

| | |
|-----------------------------|-----------------------|
| Ethische beoordeling | Positief advies |
| Status | Werving gestart |
| Type aandoening | - |
| Onderzoekstype | Interventie onderzoek |

Samenvatting

ID

NL-OMON22465

Bron

NTR

Verkorte titel

epilogue

Aandoening

scar related ventricular tachycardia

dutch: ventrikel tachycardie

Ondersteuning

Primaire sponsor: ErasmusMC

Overige ondersteuning: medtronic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

We hypothesize endo/epicardial substrate homogenization in a first approach to be superior to endocardial substrate homogenization alone, in terms of recurrence on follow-up.

Onderzoeksopzet

2 years follow-up

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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) echocardiography 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

Onderzoeksopzet

Opzet

| | |
|------------------|-------------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blinding: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

Deelname

| | |
|-------------------------|----------------------|
| Nederland | |
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-06-2015 |
| Aantal proefpersonen: | 125 |
| Type: | Verwachte startdatum |

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 20-01-2015 |
| Soort: | Eerste indiening |

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

| Register | ID |
|----------------|----------------|
| NTR-new | NL4989 |
| NTR-old | NTR5136 |
| Ander register | MEC : 2014-248 |

Resultaten