Catheter ablation of ventricular tachycardia in patients with non-ischemic cardiomyopathy

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Recurrent ventricular tachycardia (VT) is an important cause for mortality and morbidity in patients with left dominant non ischemic cardiomyopathy (NICM). Since implantable cardioverter defibrillators (ICDs) may only terminate and not prevent...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21307

Bron
NTR

Aandoening

Ventricular tachycardia, non-ischemic cardiomyopathy, catheter ablation.

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Biosense Webster - funding for data management (eg. database maintainance)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint will be a composite of death and sustained VT recurrence as registered by ICD or surface electrocardiogram during follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

Catheter ablation (RFCA) is an increasingly important treatment modality for patients with life threatening ventricular tachycardia because of non-ischemic cardiomyopathy. Despite widespread use of this treatment modality NICM large number and multicenter data regarding patient selection, safety and efficacy of this treatment modality in this population are lacking. This multicentre registry was designed to provide insight in the current use of RFCA for VT in a large group of patients with left dominant NICM. The primary objectives are to assess the safety, acute success and long-term efficacy of RFCA using state-of-the-art technology in this patient population. In addition this registry aims to identify predictors for VT recurrence based on patient characteristics and detailed assessment of the substrate for VT to enhance individualized patient selection.

Doel van het onderzoek

Recurrent ventricular tachycardia (VT) is an important cause for mortality and morbidity in patients with left dominant non ischemic cardiomyopathy (NICM). Since implantable cardioverter defibrillators (ICDs) may only terminate and not prevent recurrent VT, treatment strategies that prevent VT are of increasing importance. Radiofrequency catheter ablation (RFCA) has the potential to prevent VT recurrence by modifying its underlying substrate, myocardial fibrosis.

Most studies evaluating RFCA to treat recurrent VT in patients with structural heart disease were performed in patients with ischemic cardiomyopathy (ICM). Current recommendations for strategies, targets and endpoints of RFCA for VT in patients with structural heart disease rely mainly on these data.

Electrophysiological mapping and magnetic resonance imaging (MRI) data show however that there are important differences between ischemic- and non-ischemic cardiomyopathy with regard to type, localization and extend of myocardial fibrosis, which is the substrate of VT and target for RFCA.
Until now only single center studies including a limited number of patients have been performed to evaluate the efficacy of RFCA in patients with left dominant NICM. Using evolving techniques over time and studying a heterogeneous patient population these studies have reported 42-71% freedom of VT over varying follow-up periods. In comparison to ICM successful RFCA in patients with NICM may often require the use combined endo- and epicardial mapping.

Despite the increasing use of RFCA in patient with NICM large number and multicenter data

regarding patient selection, safety and efficacy of this treatment modality in this population are lacking.

This multicentre registry was designed to provide insight in the current use of RFCA for VT in a large group of patients with left dominant NICM. The primary objectives are to assess the safety, acute success and long-term efficacy of RFCA using state-of-the-art technology in this patient population. In addition this registry aims to identify predictors for VT recurrence based on patient characteristics and detailed assessment of the substrate for VT to enhance individualized patient selection.

Onderzoeksopzet

Patients will be included during a period of 2 years. We anticipate at least 12 patients to be enrolled at each participating center per year. Enrolling at this rate would permit inclusion of >200 patients during this period. Minimum follow-up of 1 year will be registered.

Onderzoeksproduct en/of interventie

The study will register:

• Baseline data including contrast enhanced MRI en echocardiography data.

• RFCA including induction protocol, electroanatomical maps, mapping and ablation strategy and acute success.

• Follow-up data including ICD interrogation reports at 6 months intervals.

All data are anonymized. All procedures and data recorded are part of routine (state-of-the-art) clinical practice.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• age >18jr

• sustained ventricular tachycardia within 6 months before enrolment

• non-ischemic dominant left ventricular cardiomyopathy (dilated and/or systolic dysfunction)

• accepted for radiofrequency catheter ablation of VT (intention to treat)

• informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• prior myocardial infarction

• significant coronary artery disease (>75% stenosis in any major coronary artery)

• right dominant cardiomyopathy

• hypertrophic cardiomyopathy

• LV non-compaction cardiomyopathy

• restrictive cardiomyopathy

• (sub)acute myocarditis

• cardiac sarcoidosis

• Chagas disease

• tachycardia-induced cardiomyopathy

• primary significant valve disease

• congenital heart disease

• prior valve replacement

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2013
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4612
NTR-old	NTR4763
Ander register	: VT_NICM_2013lumc

Resultaten