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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

## **Summary**

### ID

NL-OMON21307

Source NTR

#### **Health condition**

Ventricular tachycardia, non-ischemic cardiomyopathy, catheter ablation.

### **Sponsors and support**

**Primary sponsor:** Leiden University Medical Center **Source(s) of monetary or material Support:** Biosense Webster - funding for data management (eg. database maintainance)

### Intervention

### **Outcome measures**

#### **Primary outcome**

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

#### Secondary outcome

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• Acute procedural success as determined by programmed electrical stimulation at the end of RFCA

- Procedural complications
- Burden of VT during follow-up

• Type, localization and extend of myocardial fibrosis in relation to procedural success and VT recurrence

## **Study description**

#### **Background summary**

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.

### **Study objective**

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

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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.

### Study design

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.

### Intervention

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-theart) clinical practice.

## Contacts

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## **Eligibility criteria**

## **Inclusion criteria**

- 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

### **Exclusion criteria**

- prior myocardial infarction
- significant coronary artery disease (>75% stenosis in any major coronary artery)
- right dominant cardiomyopathy
- hypertrophic cardiomyopathy
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- 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

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-07-2013
Enrollment:	200
Туре:	Anticipated

## **Ethics review**

### Not applicable

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## **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	NL4612
NTR-old	NTR4763
Other	: VT_NICM_2013lumc

## **Study results**