Renal Nerve Stimulation and Renal Denervation in Patients with Sympathetic Ventricular Arrhythmias

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This study will investigate the effects of renal nerve stimulation before and after percutaneous transluminal renal denervation on cardiac excitable properties including induction of ventricular tachy-arrhythmias before and after renal denervation...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44978

Source
ToetsingOnline

Brief title
Redress VT

Condition

- Other condition
- Cardiac arrhythmias

Synonym
Sympathetic ventricular tachy-arrhythmias

Health condition

central autonomic nervous system

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: maatschap cardiologie Zwolle

Intervention

Keyword: ARVC, CPVT, renal denervation, renal nerves stimulation

Outcome measures

Primary outcome

Induction of ventricular arrhythmias in response to renal nerve stimulation prior to renal denervation and absence of ventricular arrhythmias in response to renal nerves stimulation after renal denervation.

Induction of ventricular arrhythmia during exercise stress testing performed 6 months after renal denervation.

Secondary outcome

Time to first detection of ventricular arrhythmia or appropriate ICD therapy with the monitoring period starting immediately after the intervention.

Changes in ventricular refractoriness and inducibility of ventricular arrhythmias to programmed electrical stimulation in the setting of routine electrophysiological study before and after renal denervation.

Time to first detection of ventricular arrhythmia or appropriate ICD therapy, with the monitoring period starting immediately after the intervention.

Ventricular arrhythmia burden after 6 and 12 months of follow-up in patients with ICD or continuous rhythm monitoring with a loop recorder. The monitoring period starts immediately after the intervention.

Blood pressure at 6 and 12 months after the intervention, and change in blood

pressure compared to measurement before the intervention

(Supra-)Ventricular arrhythmias, heart rate and blood pressure response changes induced by exercise testing

Changes in heart rate variability measures tested by Holter monitoring compared to measurement before the intervention.

Changes in prevalence of events (hospital admission for VT or appropriate ICD-shock) in the period of one year after intervention compared to a one year period before intervention.

Study description

Background summary

Sympathetic activity plays an important role in the pathogenesis of ventricular tachyarrhythmia. Emotional, physiological and physical stress is associated with increased rates of sudden cardiac death. Previous studies have shown evidence of significant heritable influences on individual responses to adrenergic stimulation. Catheter-based renal sympathetic denervation (RDN) is a novel treatment option for patients with resistant hypertension, proved to reduce local and whole-body sympathetic activity. This study will focus on patients with sympathetically driven ventricular tachy-arrhythmias in the setting of catecholaminergic polymorphic ventricular tachycardia (CPVT), long QT syndrome, arrhythmogenic right ventricular cardiomyopathy (ARVC), hypertrophic cardiomyopathy (HCM), dilated non-ischemic cardiomyopathy (DCM) and ischemic cardiomyopathy (ICM).
Heritable cardiac diseases associated with ventricular tachy-arrhythmias such as CPVT and long QT syndrome are characterized by episodic palpitations and/or (near-) syncope occurring during exercise or acute emotion in individuals without structural cardiac abnormalities.
ARVC is an acronym for a genetically heterogeneous group of cardiomyopathies, characterised by structural and functional abnormalities of the right and left ventricle. ARVC patients usually present with ventricular arrhythmias and in advanced stages heart failure may occur. Ventricular arrhythmias in ARVC patients is often associated with physical exercise. Anti-arrhythmic medication is not effective in selected patients with symptomatic ARVC and histories of ventricular arrhythmia or cardiac arrest. In asymptomatic ARVC gene carriers sudden cardiac death may be the first clinical manifestation.

HCM is a genetic cardiomyopathy characterized by abnormal thickening of the ventricular wall, which may lead to obstruction of the left ventricular outflow tract (LVOT). Patients may be asymptomatic, but may experience breathlessness due to obstruction of the LVOT. HCM is also a predisposition to ventricular arrhythmia. The ventricular arrhythmias may even continue despite surgical treatment of HCM by myotomy.
DCM is a type of cardiomyopathy characterized by a global weakness of the cardiac muscle with dilating of the left ventricle resulting in heart failure. Coronary artery disease has been excluded in these patients to differentiate DCM from ICM.
ICM is a type of cardiomyopathy induced by ischemic events like acute coronary syndromes or the global diminished ventricular function due to three vessel disease warranting coronary artery bypass graft surgery. What these cardiomyopathies have in common is an increased incidence of ventricular arrhythmia. In patients with a left ventricular ejection fraction (LVF) of <35% a ICD is indicated. Some patients present with therapy refractory ventricular arrhythmia despite optimal medical therapy. In a small case series with 2 ischemic and 2 non-ischemic cardiomyopathy RDN was added to VT ablation. This small series has shown benefit of RDN on top of VT ablation. Not much is known of the anti-arrhythmic effect of RDN without VT ablation in these types of patients.

Study objective

This study will investigate the effects of renal nerve stimulation before and after percutaneous transluminal renal denervation on cardiac excitable properties including induction of ventricular tachy-arrhythmias before and after renal denervation in six studies, i.e. patients with CPVT, long QT syndrome, ARVC, HCM, DCM or ICM.
The aim of the six studies is to assess the anti-arrhythmic effects of renal denervation in patients with sympathetic vetricular tachy-arrhythmias in a controlled fashion.

Study design

Investigator initiated, multi centre, pretest-posttest designed study.

Intervention

Renal denervation is a safe therapy for therapy resistent hypertension. Succesrate is more than 80% as treatment for therapy resistant hypertension. Complication risk is <1%. Renal denervation is performed with patients with "drug refractory" sympatic ventricular arrhythmia, with positive results described in publications. No randomised controlled studies concerning RDN with patients with sympathetic ventricular arrhythmia have been done yet.

Study burden and risks

We expect that RDN is successful in preventing sympathetic ventricular arrhythmia in drug refractory patients, and that the addition of RDN to optimal pharmacological therapy will be effective in the prevention of sympathetic ventricular arrhythmias.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with recurrent sympathetic ventricular arrhythmia despite optimal pharmacological therapy.
Patients with CPVT or certain types of long QT syndrome, ARVC, HCM, DCM or ICM. Patients

should use adequate beta-blocker dose or should be intolerant for anti-arrhythmic medication.
Patient is an acceptable candidate for renal denervation treatment
Patient is 18-85 years of age
Documentation of ventricular arrhythmia (ECG, rhythm strip or ICD interrogation)

Exclusion criteria

Contraindication to anticoagulation therapy or heparin.
Previous selective cardiac sympathetic denervation or previous renal denervation procedure.
Acute coronary syndrome, cardiac surgery, PCI or stroke within 3 months prior to enrolment.
Untreated hypothyroidism or hyperthyroidism.
More than grade 1/3 valvular regurgitation and/or significant valve stenosis (moderate or severe).
Severe LV dysfunction (LVEF <20% and/or grade 3/4 diastolic dysfunction)
Planned cardiovascular intervention.
Renal artery stenosis >50% of the arterial lumen, or renal artery lumen <=3 mm.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	13-02-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-09-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-09-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-08-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-03-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24558
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT02856373
CCMO	NL47301.075.13
OMON	NL-OMON24558