Renal Nerve Stimulation and renal Denervation in Patients with sympathetic Ventricular Arrhytmias.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24558

Source
Nationaal Trial Register

Brief title
Redress VT

Health condition

Patients with CPVT or certain types of long QT syndrome or ARVC.

Sponsors and support

Primary sponsor: Isala, Zwolle
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

-Main procedural study endpoint will be: Induction of ventricular arrhythmias in response to renal nerve stimulation prior to renal denervation and absence of renal nerves stimulation induced ventricular arrhythmias after renal denervation.

-Main clinical study endpoint will be: development of ventricular arrhythmia during exercise stress testing performed 6 months after randomization.

Secondary outcome

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

2. 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.

3. 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 in the RDN group and after randomization in the control group.

4. Blood pressure at 6 and 12 months after the intervention, and change in blood pressure compared to measurement before the intervention

5. (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.

Study description

Background summary

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 and refractory ventricular arrhythmias, HCM, DCM or ICM. The aim of this study is to assess the anti-arrhythmic effects of RDN in six studies of patients with sympathetic ventricular tachy-arrhythmias.

Study objective

This study wil investigate the effects of renal nerve stimulation before and after percutaneous transluminal renal denervation on cardiac excitable properties including induction of ventricular tachy-arrhytmias before and after renal denervation in 3 studies, i.e. patients with CPVT, long QTsyndrome and ARVC and refractory ventricular arrhythmias. The aim of this study is to asses te anti-arrhythmic effects of renal denervation (RDN group) compared to optimal medical therapy (control group) in these 3 studies of patients with sympathetic ventricular tachy-arrhytmias in randomized controlled fashion.

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

Study design

6 months, 12 months

Intervention

Renal artery mapping and renal denervation:
A. Catheter mapping of renal arteries and the renal sympathetic nerve distribution with fluoroscopic and nonfluoroscopic 3D navigation systems (Philips EP Navigator and St Jude Ensite Velocity systems) in patients with sympathetic ventricular arrhythmias.Clinical and biological responses of transluminal electrical renal nerve stimulation performed at different segments of each artery. We speculate that ventricular arrhythmias will occur in response to sympathetic nerve stimulation in the renal arteries and after renal denervation this response will be diminished or abolished.
B. Renal denervation ablation sites will be identified with electrical mapping and renal denervation will be guided by the pacing maneuvers in patients with drug refractory sympathetic ventricular arrhythmias.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with recurrent sympathetically driven ventricular arrhythmia despite optimal pharmacological therapy. Patients should be diagnosed with CPVT and certain types of long QT syndrome, ARVC, HCM, DCM and ICM. Eligible patients will be in the age category of 18-85 year.

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 enrollment
Untreated hypothyroidism or hyperthyroidism. More than grade 1/3 valvular regurgitation and/or signifant valve stenosis. Severe LV dysfunction. Planned cardiovascular intervention.
Renal artery stenosis >50% of the arterial lumen, or renal artery lumen< 3 mm

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2014
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 30-01-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44978
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4240
NTR-old	NTR4385
CCMO	NL47301.075.13
OMON	NL-OMON44978

Study results

Summary results
N/A