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

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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...

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

Samenvatting

ID

NL-OMON24558

Bron
Nationaal Trial Register

Verkorte titel
Redress VT

Aandoening

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

Ondersteuning

Primaire sponsor: Isala, Zwolle
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 months, 12 months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2014
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	30-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44978
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A