Nierdenervatie als behandeling van hoge bloeddruk na niertransplantatie.

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We hypothesize that catheter based selective renal denervation of the native kidneys in renal transplant recipients will improve blood pressure control and diminish the number of antihypertensive drugs.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23051

Bron
Nationaal Trial Register

Verkorte titel
CRESCENT

Aandoening

therapy resistant hypertension, kidney allograft recipients.
(therapie resistente hypertensie, niertransplantatiepatienten)

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Dutch Kidney Foundation (Nierstichting Nederland)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in daytime ambulatory blood pressure after 6 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In patients with a renal allograft, hypertension is a major etiological factor for cardiovascular morbidity, mortality and allograft nephropathy. Controlling hypertension in patients with a renal allograft is therefore crucial. There is a pressing, yet currently unmet clinical need for new blood pressure lowering strategies in renal allograft recipients. The diseased native kidneys are major contributors to hypertension, through neuro-hormonal up-regulation that leads to high levels of renin and sympathetic activity. Recently a catheter-based approach has been developed to disrupt renal sympathetic nerves. Currently this innovative technique has only been tested to lower blood pressure in therapy resistant hypertensive patients without significant renal disease. We hypothesize that catheter based selective renal denervation of the native kidneys in renal transplant recipients will improve blood pressure control and diminish the number of antihypertensive drugs.

Objective:

To test the efficacy and safety of renal sympathetic denervation therapy as a treatment of posttransplant hypertension with a special focus on preservation of renal allograft function.

Study design:

We propose an intervention study on 20 renal transplant recipients. All patients will receive standard protocolized antihypertensive treatment prior to, and during the study. Patients will be followed for 6 months after the intervention.

Study population:

Inclusion criteria are a renal allograft in situ since > 6 months with a measured creatinine clearance >35 ml/min, and a diuresis > 200ml/day of the native kidneys at time of transplantation or radiological evidence of residual flow in the renal arteries indicating that they are accessible for the intervention and have a daytime blood pressure >140/90 mmHg (assessed by 24-hours ambulatory measurement) while on >3 antihypertensive medications in maximal tolerated dose, including a diuretic.

Intervention:

Prior to study-inclusion all patients will receive standard protocolized hypertension treatment based on the National Kidney Foundation Kidney Disease Quality Outcomes Quality Initiative guidelines (2004). Renal sympathetic denervation is achieved by the interventional radiologist percutaneously entering the lumen of the main renal artery of each of the native kidneys, with a catheter connected to a radiofrequency generator. He applies 6-8 radiofrequency ablations within each renal artery. The procedure is performed in an outpatient clinic setting and patients receive standard measures for prevention of contrast nephropathy.

Main study parameters/endpoints:

Primary endpoint is blood pressure reduction after 6 months (day time blood pressure assessed by 24-hours ambulatory measurement). Secondary outcomes include changes in renal sympathetic innervation (by 123I-MIBG scintigraphy), systemic sympathetho-humoral activity (by peroneal microneurography and plasma catecholamines and rennin and aldosterone activity), measured creatinine clearance, proteinuria, number of anti-hypertensive drugs needed and quality of life and adverse events. Feasibility aspects include number of ablation pulses, duration of the intervention and total amount of radio contrast agent (ml).

Doel van het onderzoek

We hypothesize that catheter based selective renal denervation of the native kidneys in renal transplant recipients will improve blood pressure control and diminish the number of antihypertensive drugs.

Onderzoeksopzet

Primary and secondary measurement: At inclusion and after 6 months.

Onderzoeksproduct en/of interventie

Catheter based renal denervation of the native kidneys (Symplicity system, Medtronic). Renal nerve ablation is achieved in a single 40 minute catheterisatioin session.

Contactpersonen

Publiek

Department of Nephrology
Academic Medical Center at the University of Amsterdam
C.T.P. Krediet
Amsterdam
The Netherlands

Wetenschappelijk

Department of Nephrology
Academic Medical Center at the University of Amsterdam
C.T.P. Krediet
Amsterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Renal graft in situ since > 6 months, measured creatinine clearance >35 ml/min and;

2. A diuresis > 200ml/day of the native kidneys at time of transplantation or radiological evidence of residual flow in the renal arteries indicating that they are accessible for the intervention and;

3. Day time blood pressure >140/90 mmHg (assessed by 24-hours ambulatory measurement within 3 months prior to inclusion in the study, as is regularly performed in the nephrology outpatient clinic);

4. Treated according to National Kidney Foundation Kidney Disease Quality Outcomes Quality Initiative guidelines (2004), i.e. having been advised to minimize salt intake and using >3 antihypertensive medications in maximal tolerated dose, including a diuretic or ≤3 antihypertensive medications in case of confirmed intolerance to other antihypertensive medications". Medications and their dosages should not have been changed since the measurement.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. (Planned) pregnancy, lactation;

2. Life expectancy < 1 year;

3. Contraindications for (relative) hypotensive episodes i.e. haemodynamically significant valvular disease, documented transient ischemic attacks or angina pectoris during relative hypotension;

4. Heart failure, NYHA class III-IV; chronic Lung Disease Gold III-IV;

5. Major complications during previous radiological interventions (i.e. allergy to contrast agent, cholesterol embolism);

6. (Reno) vascular abnormalities in any part of the catheter access (including the aortic-iliac tract) route that impede the procedure of renal denervation;

7. Use of vitamine K antagonists or other (non-aspirin) form of anti-coagulatory therapy with an absolute indication (i.e. that cannot be temporarily stopped);

8. Implantable cardioverter defibrillator (ICD) in situ;

9. Planned surgery within the next six months;

10. Drugs- or alcohol abuse;

11. Inability to give informed consent.

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:	Anders
(Verwachte) startdatum:	01-12-2012
Aantal proefpersonen:	20

Type: Onbekend

Ethische beoordeling

Positief advies
Datum: 20-02-2013
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39908
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3696
NTR-old	NTR3866
CCMO	NL42843.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39908

Resultaten

Samenvatting resultaten
n/A