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	Niet van toepassing
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29017

Bron
Nationaal Trial Register

Verkorte titel
CRESCENT

Aandoening

Therapy resistant hypertension
renal allograft recipients

Ondersteuning

Primaire sponsor: Department of Nephrology
Academic Medical Center at the University of Amsterdam
Overige ondersteuning: Nederlandse Nierstichting
other applications pending

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change daytime blood pressure after 6 months after renal denervation assessed by ambulatory blood pressure measurement; compared to continued standard care (i.e. comforming to National Kidney Foundation Kidney Disease Quality Outcomes Quality Initiative guidelines).

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 with a special focus on preservation of renal allograft function.

Study design:

We propose a randomized controlled clinical trial (intervention group n=20; controls n=20). Intervention and control groups will receive standard protocolized antihypertensive treatment prior to, and during the trial. The intervention group will receive renal denervation in addition to standard treatment.

Study population:

Inclusion criteria are a renal allograft in situ since > 6 months with an estimated GFR >35

ml/min/ 1,73m2 and a diuresis > 200ml/day of the native kidneys at time of transplantation (to ensure presence of vital neuro-hormonally active kidney tissue) and 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), eGFR, proteinuria, number of anti-hypertensive drugs needed and quality of life and adverse events.

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.

The control group will receive care as usual.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Renal graft in situ since > 6 months, estimated GFR >35 ml/min/1,73m2 and;

2. Diuresis of the native kidneys at transplant >200 ml/day (to ensure the presence of vital kidney that could be affected by renal nerve ablation) and;

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

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. 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 ischaemic attacks or angina pectoris during relative hypotension;

4. Complications during previous radiological interventions (i.e. allergy to contrast agent, cholesterol embolism);

5. (Reno)vascular abnormalities in any part of the catheter access route (including severe femoral or renal artery stenosis and atherosclerosis, previous renal stenting or angioplasty, or known dual renal arteries);

6. Use of vitamine K antagonists or other (non-aspirin) form of anti-coagulatory therapy.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-11-2011
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2856
NTR-old	NTR2998
Ander register	ABR : 37711
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A