SYMPATHY-NTX study Catheter-based Renal Sympathectomy for Hypertension after Kidney Transplantation - a feasibility study.

Published: 16-09-2015
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Objective: To test the efficacy and safety of percutaneous renal sympathetic denervation of the native kidneys in the treatment of uncontrolled hypertension in kidney transplant recipients.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON42071

Source
ToetsingOnline

Brief title
SYMPATHY-NTX study

Condition

- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym
therapy resistant hypertension in renal transplant recipients

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hypertension, kidney transplantation, renal denervation

Outcome measures

Primary outcome

Main study parameters/endpoints: Primary endpoint is the change in blood pressure after 6 months (mean day time systolic blood pressure assessed by 24-hour ambulatory measurement).

Secondary outcome

Secondary outcomes include changes in office blood pressure, changes in antihypertensive treatment, plasma catecholamines, renin and aldosterone, eGFR and 24h proteinuria, Moreover, compliance with antihypertensive treatment compliance will be measured using a questionnaire and by detection of antihypertensives in a blood sample.

Study description

Background summary

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. Despite large patients- and doctors efforts, hypertension control is insufficient in many kidney transplant 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 (METC protocol ID 12-540). 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 needed. Before embarking on a large trial, we propose a feasibility study to obtain estimates of effect and to assess the feasibility of the procedure in this patient group.

Study objective

Objective: To test the efficacy and safety of percutaneous renal sympathetic denervation of the native kidneys in the treatment of uncontrolled hypertension in kidney transplant recipients.

Study design

Study design: We propose an intervention study in 20 kidney transplant recipients. Renal denervation will be added to usual care in all participants. Patients will be randomized to renal denervation directly after inclusion or after 6 months. Both groups will be followed for one year.

Intervention

Intervention: All patients will continue to receive usual antihypertensive treatment according to prevailing guidelines. Percutaneous renal denervation of the native kidneys will be performed at the time point determined by the randomization procedure.

Study burden and risks

Renal denervation is achieved by radio-frequency ablation during catheterisation of the renal arteries. The risks of catheterisation are bleeding, infection and contrast-agent induced nephropathy. The actual burden of the ablation procedure is that it causes visceral pain that will be treated with appropriate analgesics. Furthermore, the study requires extra visits for blood pressure measurements and extra blood drawing. The benefit could be improvement of blood pressure control. There is a sound theoretical background for application of the renal denervation procedure in kidney transplant recipients with diseased native kidneys in situ supporting the performance of a study in this patient group. Over 120 RDN procedures have been performed in the UMCU so far with only few minor complications (mostly bleeding at the puncture site).

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

- Age 18-75 years
- First kidney transplant in situ >6 months prior to randomization
- Urine measured creatinine clearance * 30 ml/min
- Radiological evidence for residual flow in the renal arteries indicating that they are accessible for the intervention
- Mean day-time systolic blood pressure of at least 135 mmHg (using ambulatory blood pressure monitoring) despite the use of at least 3 antihypertensive drugs, or with documented intolerance or contraindication for to 2 or more of the 4 major classes of antihypertensive drugs (ACEi/ARB, calcium channel blockers, betablockers and diuretics) thus being unable to be treated with 3 antihypertensives.
- Hemodynamically significant stenosis of the renal artery of the graft as a cause of therapy resistant hypertension has to be (have been) excluded (using MRI).

Exclusion criteria

- (Planned) pregnancy, lactation
- Life expectancy <1 year
- Contraindications for (relative) hypotensive episodes i.e. hemodynamically significant valvular disease, documented transient ischemic attacks or angina pectoris during relative hypotension
- Heart failure, NYHA class III-IV; chronic lung disease Gold III-IV
- Major complications during previous radiological interventions (i.e. allergy to contrast agent, cholesterol embolism)
- (Reno) vascular abnormalities in any part of the catheter access (including the aortic-iliac tract) route that impede the procedure of renal denervation
- 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)
- Implantable cardioverter defibrillator (ICD) in situ
- Planned surgery within the next six months
- Drugs- or alcohol abuse
- Inability to give informed consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	16-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL52243.041.15