Treatment of severe hypertension in end-stage renal failure: Effect of renal denervation in dialysis patients and patients with renal transplant.

Published: 01-05-2013
Last updated: 24-04-2024

The purpose of this study is to demonstrate the effectiveness of renal denervation in lowering blood pressure in patients with therapy-resistant hypertension and end-stage renal disease who are on dialysis or who have a renal transplant.

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON39799

Source
ToetsingOnline

Brief title
Renal denervation in ESRF

Condition

- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: Eigen budget ziekenhuis

Intervention

Keyword: Dialysis, End-stage renal failure, Renal denervation, Renal transplant

Outcome measures

Primary outcome

Primary study outcome is the degree of blood pressure drop in 6 months after renal denervation. Measurements will be performed with ambulatory blood pressure measurement during 24 hours. Also changes in medication regimen will be registered.

Secondary outcome

Effect of renal denervation on cardiac mass and function. Changes in sympatic nerve activity measured by EMG of the nervus peroneus. Changes in hormonal levels related to blood pressure regulation.

Study description

Background summary

The prevalence of end-stage renal failure is increasing. Hypertension is a significant problem in patients with renal failure who are on dialysis or have a renal transplant. 60 to 80% of these patients have hypertension. In a significant proportion of these patients anti-hypertensive medication alone is not sufficient to achieve acceptable blood pressures. Recent development of new ablation catheters could be helpful in this. By inactivating the efferent and afferent fibers of the sympathetic nervous system along the renal artery, it may be possible to reduce the neurohormonal activity of the native kidneys and with this a reduction of the blood pressure can be achieved.

Study objective

The purpose of this study is to demonstrate the effectiveness of renal denervation in lowering blood pressure in patients with therapy-resistant hypertension and end-stage renal disease who are on dialysis or who have a renal transplant.

Study design

Single-centre, non-randomised, prospective cohort study.

Intervention

Renal denervation with an ablationcatheter. The renal arteries of the native kidneys will be denervated.

Study burden and risks

Participants might benefit through a reduction in hypertension. This may result in a decrease in number and / or amount of antihypertensive medication. Hypertension has a detrimental long term effect on cardiac function. It can lead to heart failure and myocardial hypertrophy. Lowering the blood pressure results in reduced rates of cardiovascular events. So far, no long-term effects of renal denervation are known.

Procedural complications can include the following:
Renal denervation can cause damage to the treated artery, resulting in an occludion. However, this has no further consequences in this group of patients since their native kidneys have no or hardly any residual function. Furthermore, allergic reaction to the injected contrast or groin hematoma caused by the puncture can occur.

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

Patients with a renal transplant or on dialysis with therapy resistent hypertension, as defined in current guidelines (SBP >160 mmHg with the use of >=3 antihypertensive medication).

Exclusion criteria

Patient with a renal artery stent. Pregnant or pregnancy desire. Known allergy for iodine contrast. Age <18 year.
Patients with contraindication for MRI can participate. in these patients there will be no MRI examinations.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-05-2013
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL42796.101.12