Endovascular renal sympathetic denervation versus spironolactone for treatment-resistant hypertension: a randomized, multicentric study

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Comparison of the additional blood pressure lowering effect of RFSD with that of the addition of spironolactone in patients with a persistant increased blood pressure despite treatment with three different antihypertensive agents.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37880

Source
ToetsingOnline

Brief title
RRSS study

Condition

- Other condition

Synonym
High blood pressure, Hypertension

Health condition

hypertensie

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Hypertension, Renal denervation, Spironolactone

Outcome measures

Primary outcome

Difference in 24-hour ambulatory blood pressure decrease between the RFSD and

spironolactone group.

Secondary outcome

- Proportion of patients per intervention group with normalization of their

24-hour ambulatory blood pressure

- Proportion of patients per intervention group with a decrease in 24-hour

ambulatory blood pressure of >= 10 mmHg systolic and >= 5 mmHg diastolic.

- Cost effective of RFSD

- Difference in scores of quality of llife between RFSD and spironolactone group

- Predictive value of clonidine-suppressiontest for the blood pressure response

to RFSD

Study description

Background summary

Endovascular, radiofrequency, renal sympathetic denervation (RFSD) is a new treatment modality for patients with treatment-resistant hypertension. RFSD is available in various medical centers in The Netherlands. Two studies published

in the Lancet have shown that RFSD is a safe procedure with a large effect on office blood pressure, but a much smaller effect on 24-hour ambulatory blood pressure. The elevated blood pressure in patients with therapy-resistant hypertension responds often surprisingly good to the addition of mineralocorticoid receptor blocker. It is unknown whether RFSD has advantages with regard to blood pressure lowering effect, costs and quality of life compared to addition of spironolactone in patients with therapy-resistant hypertension. With this proposal we want to compare the additional blood pressure lowering effect of RFSD with that of the addition of spironolactone in patients with still an elevated blood pressure despite the use of three different antihypertensive agents. From our own experience in 14 subjects it appeared that the blood pressure response to RFSD shows a large inter-individual variation. The reason for this variation is unclear. Since it is assumed that the decrease in blood pressure in response to RFSD depends on a decrease in renal and systemic sympathetic tone it will be explored wheter the blood pressure response can be predicted by the clonidine-suppression test.

Study objective

Comparison of the additional blood pressure lowering effect of RFSD with that of the addition of spironolactone in patients with a persistant increased blood pressure despite treatment with three different antihypertensive agents.

Study design

Randomized multcentric study

Intervention

RFSD or addition of spironolacton in a maximal dose of 50 mg per day. Per treatment arm 47 evaluable patients are needed. Follow-up duration after intervention is 6 months.

Study burden and risks

At least 2 visits before and 4 visits to the otupatient department after RFSD or start of spironolactone. These visits take about 1.5 hour and consist of 1 hour blood pressure measurement, blood sampling via an infusion needle and medical consultation. In addition 24-hour urine collections 3 times. 24-hour ambulatory blood pressure recordings 3 times and 1 clonidine-suppression test for patients randomized for RFSD.
Patients who are randomized for RFSD are hospitalized for one night following the procedure.
Addition of spironolactone or RFSD are accepted and safe treatments for patients with refractory hypertension. Individual patients may benefit from the

interventions as their blood pressure may become better controlled.

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 between 18 and 75 yrs
Treatment-reistant hypertension
Willingness to give written informed consent

Exclusion criteria

Secondary forms of hypertension

Renal arteries not accessible to intervention
Suboptimal dosing of anthypertensive medication
White coat hypertension
Pregnancy
Renal insufficiency (GFR < 45 ml/min

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2012
Enrollment:	130
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	aldactone
Generic name:	spironolactone
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	09-12-2011
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-02-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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
EudraCT	EUCTR2011-004995-13-NL
CCMO	NL38372.078.11