

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

Source

NTR

Brief title

RRSS-trial

Health condition

Hypertension, Renal sympathetic denervation, Spironolactone.
Hypertensie, Renale sympathische denervatie, spironolacton

Sponsors and support

Primary sponsor :	Erasmus MC: Department of Radiology
Source(s) of monetary or material Support :	Not applicable

Intervention

Outcome measures

Primary outcome

Difference in 24-hour ambulatory blood pressure between spironolactone and endovascular renal denervation 6 months after intervention.

Secondary outcome

1. Proportion of patients with normalisation of ambulatory blood pressure in the two intervention groups;
2. Proportion of patients per intervention group with a decrease in 24-hour ambulatory blood pressure of at least 10 mmHg systolic and and at least 5 mmHg diastolic;
3. Predictive value of clonidin-suppression test on blood pressure response to endovascular sympathetic denervation;
4. Cost effectiveness of renal sympathetic denervation;
5. Difference in quality of life score between endovascular renal denervation and spironolactone group.

Study description

Study objective

Renal sympathetic denervation is not superior to add-on therapy with spironolactone in treatment-resistant hypertension.

Study design

Ambulatory blood pressure will be measured 6 months after intervention.

Intervention

1. Endovascular renal sympathetic denervation;
2. Addition of spironolactone to existing antihypertensive treatment.

The intervention consists either of endovascular renal sympathetic denervation or the addition of spironolactone to existing antihypertensive treatment.

Endovascular renal sympathetic denervation is a recently introduced technique. With the technique a catheter is introduced via a groin artery in the left and right renal artery.

Using radiofrequency energy the nerves surrounding the renal arteries are ablated. This is a once a time procedure lasting about 1 hour. With this technique blood pressure potentially falls and this effect is compared with the addition of spironolactone in a maximal once daily dose of 50 mg.

Patients with treatment-resistant hypertension are included. They will be randomised for endovascular renal sympathetic denervation or treatment with spironolactone.

Spironolactone is used for 6 months. The primary endpoint of this study is the difference in 24-hour ambulatory blood pressure response between the group of patients treated with endovascular denervation and the group of patients treated with spironolactone after 6 months of follow-up.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 yrs and < 75 yrs;
2. Treatment-resistant hypertension;
3. Willingness to give informed written consent.

Exclusion criteria

1. Secondary hypertension;
2. Renal arteries inaccessible for endovascular denervation;
3. Suboptimal dosing of BP lowering medication;
4. Incompliant to treatment;
5. White coat hypertension;
6. Pregnancy;
7. GFR < 45 ml/min;
8. Use of vit K antagonist that can not be discontinued for a short period;
9. Spironolactone intolerance;
10. Intolerance for one of the components of Exforge-Hydrochlorothiazide;
11. Myocardial infarction or cerebrovascular accident 3 months prior to randomization;
12. Life expectancy < 2 year.

Study design

Design

Study type : Interventional
Intervention model : Parallel

Allocation :	Randomized controlled trial
Masking :	Open (masking not used)
Control :	Active

Recruitment

NL	
Recruitment status :	Recruiting
Start date (anticipated) :	01-06-2012
Enrollment :	120
Type :	Anticipated

Ethics review

Positive opinion	
Date :	21-05-2012
Application type :	First submission

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
NTR-new	NL3297
NTR-old	NTR3444
Other	METC Erasmus MC : MEC-2011-481
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

M. Ezzahti, A. Moelker, A.H. van den Meiracker: Endovascular renal sympathetic denervation. A new treatment for treatment resistant hypertension? Hart Bulletin 2012;43:34-39.