

Comparison of renal sympathetic denervation with spironolactone in patients with still a high blood pressure despite the use of 3 different antihypertensive agents.

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26106

Bron

Nationaal Trial Register

Verkorte titel

RRSS-trial

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC: Department of Radiology

Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

Ambulatory blood pressure will be measured 6 months after intervention.

Onderzoeksproduct en/of interventie

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 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.

Contactpersonen

Publiek

Erasmus MC
A.H. Meiracker, van den
's Gravendijkwal 230
Rotterdam 3015 CE
The Netherlands
+31-10-4639222

Wetenschappelijk

Erasmus MC
A.H. Meiracker, van den
's Gravendijkwal 230
Rotterdam 3015 CE
The Netherlands
+31-10-4639222

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart

(Verwachte) startdatum: 01-06-2012
Aantal proefpersonen: 120
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 21-05-2012
Soort: Eerste indiening

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

Resultaten

Samenvatting resultaten

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.