Sympathy Redo: redo of renal denervation with a second generation device.

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The primary objective is to assess whether RDN by other devices than Medtronic added to usual care compared to usual care alone reduces BP in subjects, classified as non-responders on renal denervation, six months after RDN.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42639

Source
ToetsingOnline

Brief title
Sympathy Redo

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
high blood pressure, hypertension

Health condition

hypertensie

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: denervation, device, redo, renal

Outcome measures

Primary outcome

The endpoints are conform the endpoints formulated in the Sympathy study:

change in ABPM (average daytime SBP).

Secondary outcome

Key secondary study parameters/endpoints: 1) Change in the amount of antihypertensive medication (daily defined dose). 2) The effect of RD in subgroups: across strata of eGFR (eGFR 20-60 mL/min per 1.73m2 and eGFR>60 mL/min per 1.73m2) and across strata of baseline BP (SBP 140-160mmHg and >160mmHg). 3) Change in office BP.

Further, information will be collected concerning :

* The effect of RDN on renal function and the incidence of peri-procedural complications

* The long term effect of RDN on fatal- and non-fatal cardiovascular events

* Cost-effectiveness of the procedure,

* Impact of RDN on quality of life

* Budget impact analyses

* Explorative analysis will be done of predictors of effect and of mechanisms of the BP-lowering effect.

Study description

Background summary

Hypertension is a major and growing problem worldwide. Overactivity of the sympathetic nervous system is identified as a major cause in the development of hypertension. The sympathetic renal nerves play an important role in the process of increased sympathetic activity. Studies have shown that renal denervation, the disruption of the nerves that connect the kidneys to the central nervous system, is an effective and safe treatment for patients with resistant hypertension (systolic blood pressure of at least 140 mm Hg) despite the use of at least 3 antihypertensive agents. However, there are two groups that that we can differentiate: 1), the group which has a clear effect of the treatment, and 2) a group that has little or no effect of the treatment. At present, on the basis of new insights, the medical devices are adjusted. Studies with this new and improved device show a promising fall in blood pressure in patients with elevated blood pressure. Also in the group of patients who have been previously treated with the Symplicity catheter of Medtronic (first generation catheter), renal denervation again with a new and improved catheter (second generation catheter), lowered blood pressure.

Study objective

The primary objective is to assess whether RDN by other devices than Medtronic added to usual care compared to usual care alone reduces BP in subjects, classified as non-responders on renal denervation, six months after RDN.

Study design

This study is a pilot study. The study design is equal to the Sympathy study (METC-number 12-540), a randomized controlled trial, therefore baseline and follow-up visits are according Sympathy protocol.

Intervention

The intervention group will, additional to usual care, be treated with RDN. Usual care is determined as therapy of hypertension in line with cardiovascular disease prevention guidelines. The control group will be treated according to usual care.

Study burden and risks

Published studies have reported an excellent safety profile of RDN. Procedure related complications have been few in number and of the type expected for an

endovascular procedure utilizing femoral arterial access. Most of the complications consisted
of groin complications and a single renal artery dissection that occurred prior to delivery of
RF energy by the RD catheter. These events were treated with standard measures and all
resolved without sequelae. Long term vascular safety has been demonstrated by follow-up
imaging studies which showed no lesion formation at any of the RF energy treatment sites
examined.

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

1.Individual is *18 years of age.
2. Individual has a mean day-time SBP * 135 mmHg, as determined with the use of ABPM, while the patient uses 3 or more antihypertensive agents for at least 3 months prior to inclusion or with documented intolerance to 2 or more of the 4 major classes antihypertensive drugs (ACE/ARB, Calcium channel blocker, Beta Blocker, Diuretic) and no possibility to take 3 anti-hypertensive drugs.
3. Individual has been treated with renal denervation as treatment for hypertension * 12 months prior for inclusion.
4. Individual has been treated with renal denervation, performed with the Symplicity Flex catheter.
5. Individual has a decrease in systolic ABPM < 10 mmHg compared to baseline.;The inclusion criteria are the same as for the Sympathy study, plus the addition of the last three criteria.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:;1. Individual is unable or unwilling to sign informed consent.
2. Individual has a treatable secondary cause of hypertension
3. Individual has an eGFR below 20 mL/min/1.73m2 using the MDRD calculation.
4. Individual has renal artery anatomy that is ineligible for treatment.
5. Individual has any serious medical condition, which in the opinion of the investigator, may adversely affect the safety and/or effectiveness of the participant or the study.
6. Individual is pregnant, nursing or planning to be pregnant.
7. Individual participates (participated) in the Sympathy study.;The exclusion criteria are the same as for the Sympathy study plus the last criteria.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Renal denervation
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	15-12-2015
Application type:	First submission
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	NL54632.041.15