SYMPATHY: Renal sympathetic denervation as a new treatment for therapy resistant hypertension: from rescue to resolve.

Published: 03-09-2012
Last updated: 26-04-2024

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

Summary

ID

NL-OMON37568

Source
ToetsingOnline

Brief title
SYMPATHY

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
hypertension high blood pressure

Health condition

hoge bloeddruk

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Medtronic,ZONMW

Intervention

Keyword: denervation, hypertension, renal, sympathetic

Outcome measures

Primary outcome

The primary effectiveness endpoint is change in office BP at six months

follow-up.

Secondary outcome

Secondary study parameters/endpoints: Incidence of achieving target BP (SBP

<140 mmHg, or <130 for diabetics), incidence of achieving a >10 mmHg reduction

in SBP, change in 24 hour ambulatory BP, change in eGFR, change in

proteinuria/albuminuria, change in Quality of life, health care costs,

non-healthcare costs and costs per Quality Adjusted Life Year.

Study description

Background summary

Hypertension is a major and growing public health concern. Chronic elevation of sympathetic nervous system (SNS) activity has been identified as a major contributor to the complex pathophysiology of (essential) hypertension. The renal sympathetic nerves play a major role in the elevation of the SNS activity. Therapeutic renal denervation (RD), the deliberate disruption of the nerves connecting the kidneys with the central nervous system, has been shown to effective and safe in patients with hypertension (SBP>160 mmHg) resistant to hypertension. The effect of RD in patients with less severe hypertension and

patients with chronic kidney disease (CKD) stage 3 to 5 is not investigated yet. We hypothesize that renal denervation also has beneficial effects in these patients.
RD is relatively expensive compared to pharmaceutical treatment. Therefore, it is important to perform an economic evaluation. We expect that the initial investments in RD may be counterbalanced by the fact that savings on direct health care costs are possible after some years, as lifelong use of multiple antihypertensive drugs will possibly be reduced or become unnecessary.

Study objective

The primary objective is to assess whether renal denervation added to usual care compared to usual care alone reduces BP (office based BP and 24-h ambulatory BP-monitoring) both in subjects with a SBP level above 160 mmHg as well as subjects with a SBP level between 140 and 160 mmHg, despite the use of three or more BP lowering drugs.
Secondary objectives are: 1) To study whether the effect of RD is similar across strata of eGFR. 2) To assess the effects renal denervation on BP lowering drug use. 3) To identify factors that relate to a beneficial response to RD (responders). 4) To study the cost-effectiveness of RD in comparison with usual care for hypertensive patients.

Study design

The trial will start enrolling patients with SBP of 140 mmHg or above (and three or more BP lowering drugs). When 3 months follow-up data on systolic BP are available for 60 patients in the group with SBP between 140 and 160 mmHg, treatment arms will be compared with respect to change in systolic arterial pressure at 3 months. In case the estimated difference in decrease of SBP is less or equal to 0 (i.e., no beneficial trend for renal denervation), recruitment for this group will terminate and only patients with SBP >= 160 mmHg will continue to be recruited up to their original total of 130.

Intervention

The intervention group will, additional to usual care, be treated with RD.
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 RD. 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. The safety profile of RD is expected to be the same for patients with a lower BP (BP >=140mmHg).

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 has a mean daytime SBP >= 135 mmHg determined with the use of 24-h or daytime ambulatory BP monitoring while the individual uses antihypertensives.
2.Individual uses at least 3 antihypertensive drugs.
3.Individual is >=18 years of age.

Exclusion criteria

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 20mL/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 has a known, unresolved history of drug use or alcohol dependency, lacks the ability to comprehend or follow instructions, or would be unlikely or unable to comply with study follow-up requirements.
8. Individual is currently enrolled in another investigational drug or device trial.

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:	260
Type:	Anticipated

Ethics review

Not approved

Date:	03-09-2012
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	NL39726.041.12