Long-term efficacy of endovascular ultrasound renal denervation in resistant hypertension: 6-year results from the ACHIEVE study

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To assess the long-term BP lowering effect of renal denervation using a dedicated circumferential ultrasound balloon catheter in patients with resistant hypertension.

Ethical review	Approved WMO
Status	Completed
Health condition type	Vascular hypertensive disorders
Study type	Observational invasive

Summary

ID

NL-OMON49583

Source
ToetsingOnline

Brief title
ACHIEVE Long-Term Follow-Up Study

Condition

- Vascular hypertensive disorders

Synonym
Hypertension; high blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ReCor Medical Incorporation

Intervention

Keyword: Hypertension, Long-term outcome, Renal denervation, Ultrasound

Outcome measures

Primary outcome

Change in 24h ambulatory systolic BP between baseline and 6 years.

Secondary outcome

Major Adverse Event (MAE) rate (including any of the following elements within

6 years: mortality, embolic events causing end organ damage, renal failure

(eGFR<15 ml/min per 1.73m2 or need for dialysis), new renal artery stenosis of

at least 70%, or hospitalization for hypertensive crisis);

6 year survival status;

change in office systolic and diastolic BP between baseline and 6 years;

change in 24h ambulatory diastolic BP between baseline and 6 years;

change in daytime systolic and diastolic ambulatory BP between baseline and 6

years;

change in nighttime systolic and diastolic ambulatory BP between baseline and 6

years;

change in office and 24h ambulatory BP measurements performed between 1 and 6

years;

change in defined daily dose (DDD) of antihypertensive drugs;

change in eGFR between baseline and 6 years.

Study description

Background summary

Hypertension remains a serious risk factor for cardiovascular morbidity and mortality. Sympathetic overactivity is one of the key contributing factors for hypertension and several sham controlled randomized controlled trial have recently shown that renal sympathetic denervation (RDN) using either radiofrequency energy or circumferential ultrasound has the ability to significantly lower blood pressure (BP) in hypertensive patients both on- and off antihypertensive medication up to 6 months. As growing evidence is available on the short-term efficacy of RDN less is known on its long-term BP lowering effects in relation to the use of antihypertensive medication.

Study objective

To assess the long-term BP lowering effect of renal denervation using a dedicated circumferential ultrasound balloon catheter in patients with resistant hypertension.

Study design

Multicentre, prospective, observational follow-up study.

Study burden and risks

All patients initially enrolled in the ACHIEVE study will be recontacted and reconsented. Patients will be invited for a single office visit. Non-invasive study measurements will be a physicial examination, an office BP measurement, a 24h ambulatory BP measurement and a medication review. To determine the estimated Glomerular Filtration Rate (eGFR) one venapunction per patient will be performed. Also a retrospective patient file review will be performed to collect BP and AE data available from earlier outpatient clinic visits.

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

- Initial enrolment in the ACHIEVE-study;
- Treated with the Paradise ultrasound renal denervation system;
- Informed consent;
- The patient agrees to follow-up.

Exclusion criteria

Not applicable.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-08-2021
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2020
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
CCMO	NL74574.078.20