Reactive Oxygen Species in trEatment-resistant hypertension treated with denervation of the sympathetic nerves

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To investigate whether renal denervation leads to a decrease in oxidative stress in patients with therapy-resistant hypertension.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vascular hypertensive disorders
Study type	Observational invasive

Summary

ID

NL-OMON38954

Source
ToetsingOnline

Brief title
The ROSE study.

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, oxidative stress

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: Hypertension, Reactive Oxygen Species (ROS), Renal Denervation

Outcome measures

Primary outcome

The effect of renal denervation on markers of oxidative stress present in

blood, urine and isolated leukocytes.

Secondary outcome

To determine whether blood pressure, insulin resistance, kidney function and

lipid profile are related to ROS production.

Study description

Background summary

Increasing evidence suggests an elevated production of reactive oxygen species (ROS) in sympathetic hyperactivity states such as hypertension, insulin resistance, heart failure, chronic kidney disease and obstructive sleep apnea. In addition, reactive oxygen species can, upon damage or ischemia, activate the local tissue renin angiotensin system (t-RAS) in a diseased organ that is innervated by the sympathetic nervous system (SNS). Moreover, both the SNS as well as RAS are reported to be involved in the pathogenesis of hypertension and hypertension related diseases. Furthermore, this dual activation could have a common initiator and several studies suggested ROS could fulfil this role. Therapeutic renal denervation (PRDN), the deliberate disruption of the nerves connecting the kidneys with the central nervous system, has been shown to be an effective means of modulating elevated SNS activity. To discover a correlation between ROS production and SNS activity in humans, the current study aims to evaluate the effect of renal sympathetic denervation on the production of ROS in patients with therapy-resistant hypertension and/or hypertension related diseases.

Study objective

To investigate whether renal denervation leads to a decrease in oxidative stress in patients with therapy-resistant hypertension.

Study design

Single centre, prospective, observational study in 30 patients.

Study burden and risks

The minimal risks associated with the measurements described are acceptable. Based on clinical experience, we do not expect any potential risks regarding this trial. Possible complications include a hematoma, (trombo)flebitis or dissection of a vein.

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 accepted for treatment with renal denervation as standard therapy for resistant hypertension.
2. Individual is *18 years of age.
3.Individual agrees to have all study procedures performed, and is competent and willing to provide written
informed consent to participate in this clinical study.

Exclusion criteria

1. Individual is excluded from treatment with pRDN.
2. Individual has an estimated glomerular filtration rate (eGFR) of <30mL/min/1.73m2, using the MDRD calculation.
3. Individual is pregnant, nursing or planning to be pregnant.
4. 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.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

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

Ethics review

Approved WMO

Date:	30-12-2013
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	NL46147.041.13