Renal denerVatiOn under anatomicaL and elecTrical guidance (VOLT)

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The principal aim of this study is the intraprocedural absence of blood pressure response to electrical stimulation post-ablation (as opposed to pre-ablation) in man in order to evaluate (effective) renal denervation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON46881

Source
ToetsingOnline

Brief title
Renal denerVatiOn under anatomicaL and elecTrical guidance (VOLT)

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anatomical, denervation, electrical, hypertension

Outcome measures

Primary outcome

To study blood pressure changes in response to electrical stimulation pre- and post-ablation in order to evaluate effective denervation.

Secondary outcome

To study the effect of renal denervation on office- and ambulatory blood pressure.

To study the effect of renal denervation on renal blood flow as expressed by renal flow reserve and resistance index.

To study the effect of renal denervation on the efferent sympathetic nervous system activity as expressed by catecholamine levels and natriuresis.

To study the effect of RDN on central sympathetic nervous activity as expressed by heart rate variability and peripheral arterial tonometry.

Study description

Background summary

Several years ago renal denervation was introduced as a promising intervention in hypertension. The initial randomised trials proved positive. However, the Symplicity HTN-3, the only randomized, sham controlled study, proved negative although a modest overall effect of RDN is suggested.The evidence for renal

sympathetic denervation (RDN) in hypertensive patients is therefore conflicting. Today, no marker or functional test to guide RDN nor to establish sufficient renal denervation exists. Renal denervation can be considered as a black box procedure.

Recently, two intriguing observations have been accomplished.
First, the distribution of renal sympathetic nerves in man has been studied, providing an anatomic map for denervation.
Second, renal nerve stimulation (RNS) showed to induce a blood pressure increase in a human hypertension model. The RNS-evoked increase was significantly blunted after RDN, thus providing an electrical map for denervation.

Study objective

The principal aim of this study is the intraprocedural absence of blood pressure response to electrical stimulation post-ablation (as opposed to pre-ablation) in man in order to evaluate (effective) renal denervation.

Study design

Pilot study, prospective open label.

Intervention

Anatomical and electrical stimulation guided renal denervation by means of radiofrequency ablation of renal sympathetic nerves.

Hyperemic flow/pressure measurement within renal artery before and after denervation

Heart rate variability measurements

Peripheral arterial tonometry

Study burden and risks

The extent of burden encompasses a regular diagnostic work-up for patients presenting with hypertension including home blood pressure measurement, serum and urine examination, echocardiography, abdominal CT and additional percutaneous renal artery denervation.

Renal denervation has become an accepted therapeutic strategy with minimal adverse events and patient discomfort.
Additional peri-procedural autonomic nerve stimulation, if potentially painful, will be addressed with opioid treatment.

Peri-procedural (hyperemic) pressure/flow measurements bear minimal risk/burden.
Patients will be sedated throughout the protocol.

Heart rate variability and peripheral arterial tonometry assesment encompasses non-invasive measurements with a very limited additional burden.

The primary risks of the renal denervation / stimulation procedure are similar to the risks of all diagnostic procedures requiring catheterization of the arteries of the body. The following are potential risks of the catheterization procedure:
- Complications at catheter insertion site in the groin (i.e., pain, bruising, pseudo aneurysm, AV fistula, infection, significant external blood loss)
- Retroperitoneal bleeding
- Vascular complications requiring surgery
- Perforation or dissection of a blood vessel, such as the renal artery
- Temporary clotting (may cause heart attack, stroke or kidney damage and may ultimately lead to incapacitation or death)
- Heart rhythm disturbances, such as a slowed heart rate
- Nausea or vomiting
- Athero-embolism resulting in distal vessel occlusion
- Complications associated with the contrast agent used during the procedure, e.g., serious allergic reaction or contrast nephropathy

Risks acciciated especially to renal stimulation and denervation are mechanical and sympathetic in origin. Possible effects are dissection and spasm, which can most likely be treated conservative. Embolisation of microthrombi with or without loss of renal function pose another small risk. Additionally, (reversible) hypotension as a result of denervation can occur.

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

Patients with evidence of hypertension, treated with at least three antihypertensive drug, of which one a diuretic

Exclusion criteria

age > 65 y
ambulantory blood pressure > 180/110 mmHg in the absence of antihypertensive medication
renal clearance < 60 ml/min (MDRD)
secundaire hypertensie

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-01-2019
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Renal denervation EnligHTN catheter
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	24-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23038
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56394.029.16
OMON	NL-OMON23038