Effect of renal denervation on Muscle Sympathetic Nerve Activity in patients with uncontrolled hypertension

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The goal of this study (mono-center study) is to study the effect of renal denervation with the EnligHTN Renal Denervation System on sympathetic nerve activity.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON41590

Source
ToetsingOnline

Brief title
Muscle Sympathetic Nerve Activity and Renal denervation

Condition

- Other condition

Synonym
Muscle sympathetic nerve activity / Nerve activity in muscle tissue

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: Hypertension, MSNA, Renal denervation, Sympathetic nervous system

Outcome measures

Primary outcome

The effect on renal denervation with the EnligHTN II catheter on MSNA.

Secondary outcome

We will include data, conducted in the EnligHTN II or Sympathy study.

Study description

Background summary

Chronic elevation of sympathetic nervous system (SNS) activity has been identified by extensive preclinical and clinical literature as a common and key factor in disease states such as hypertension, heart failure, and chronic kidney disease. The renal sympathetic nerves are a major contributor to the complex pathophysiology of elevated SNS activity and hypertension. Therapeutic renal denervation, 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 - both by reducing the sympathetic control of renal function and by removing the renal afferent sympathetic contribution to central blood pressure elevation. St. Jude Medical has developed the EnligHTN Renal Denervation System as a minimally-invasive means of achieving renal denervation. This system is comprised of a single-use catheter with expandable basket with four ablation electrodes and a radiofrequency (RF) generator. In an international multi-center study called EnligHTN II we will study the effect of renal denervation on systolic blood pressure and safety of denervation during five year follow up (13-096). Furthemore, the EnligHTN catheter is recently added as device in the Sympathy study. This proposal is a sub-study of the EnligHTN II study and Sympathy study. The goal of this sub-study (mono-center study) is to investigate the effect of renal denervation with the EnligHTN Renal Denervation System on sympathetic nerve activity.

We hypothesize that MSNA will be normalized after renal denervation in this population.

Study objective

The goal of this study (mono-center study) is to study the effect of renal denervation with the EnligHTN Renal Denervation System on sympathetic nerve activity.

Study design

This study is a sub-study of EnligHTN II study and Sympathy study. We prospectively collect data on MSNA before and after renal denervation. All patients included in EnligHTN II or Sympathy may be included in this study. However, this sub-study is not obligatory for patients included in EnligHTN II or Sympathy. Participants of EnligHTN II or Sympathy may refuse to participate in this sub-study. The participants will be recruited from our outpatient clinics.

First the patient is asked to participate in the EnligHTN II or Sympathy study. Prior to enrollment in this study, his/her eligibility to participate in the study will be checked. A complete medical history will be reviewed, physical examination will be performed and office blood pressure measurements will be recorded. If the patient meets all inclusion and exclusion criteria, he/she is eligible for the study. Secondly, the patient can be asked to participate in this sub-study. The patient will be asked to provide written informed consent for the MSNA measurements, once he/she has been fully informed about the investigation, has agreed to participate, signed and dated the patient informed consent.

This sub-study contains 2 visits:

FIRST VISIT
The first MSNA measurement will be performed, prior to the renal denervation. This visit will take about two hours. In order to maximize the value and standardization of the measurements, the patient has to be on a stable medication regime for at least three months.

SECOND VISIT
This visit will take place 6 months after the renal denervation procedure. The participant visits the day-care centre. MSNA measurements will be repeated.

Study burden and risks

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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

Included in the EnligHTN II study or Sympathy study. The patient has to be on a stable medication regime for at least 3 months.

Exclusion criteria

Exclusion criteria composed in the EnligHTN II study or Sympathy study. Patients are not on a stable medication regime for at least 3 months.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-12-2015
Application type:	Amendment
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	NL43830.041.13