# Effect of kidney denervation on Muscle Sympathetic Nerve Activity in patients with chronic kidney disease (Sub-study multi-center randomized trial SIMPLICITY)

Published: 08-01-2010 Last updated: 04-05-2024

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

# Summary

### ID

NL-OMON33226

**Source** ToetsingOnline

Brief title kidney denervation and Muscle Sympathetic Nerve Activity

## Condition

- Other condition
- Nephropathies

**Synonym** chronic kidney disease, Chronic renal diseases

#### **Health condition**

#### Hypertensie

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### **Research involving**

Human

### **Sponsors and support**

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

#### Intervention

Keyword: hypertension, Kidney denervation, sympathetic activity

#### **Outcome measures**

#### **Primary outcome**

- Muscle sympathetic nerve activity

Expected outcome:

- substantial decrease (or possibly normalization) of MSNA

#### Secondary outcome

There are no secundary parameters

# **Study description**

#### **Background summary**

Chronic elevation of sympathetic nervous system activity has been identified by extensive preclinical and clinical literature as a common and key factor in disease states such as hypertension. The kidney sympathetic nerves are a major contributor to the complex pathophysiology of elevated sympathetic nervous system activity and hypertension. Therapeutic kidney 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 sympathetic nerve activity. The effect of kidney denervation on systolic blood pressure and safety of denervation during three year follow up will be studied in a multi-center randomized trial called SIMPLICITY. As our department will be participating in the multi-center randomized trial the protocol of the study is submitted to the Ethics Committee at the UMC Utrecht. This proposal is a sub-study of SIMPLICITY study. The goal of the sub-study (mono-center study) is to investigate the effect of kidney denervation on muscle sympathetic nerve activity (MSNA).

In the past years, we have conducted studies using the microneurographic technique in order to evaluate various questions relating hemodynamics in kidney patients. This technique is considered one of the few reliable methods to quantify sympathetic activity. MSNA is the centrally originated postganglionic sympathetic nerve activity directed towards the resistance vasculature. It is usually measured in the peroneal nerve. We have extensively shown that MSNA is higher in hypertensive patients with chronic kidney disease than in controls and that presently advised medical treatment reduce but not normalize MSNA.

#### **Study objective**

In the present study, we want to investigate the effect of kidney denervation on MSNA in hypertensive patients. The central hypothesis of this project is that MSNA in hypertensive patients will decrease (or may be even normalize as in bilaterally nephrectomized patients) after kidney denervation.

#### Study design

In detail description of study protocol

First visit:

The patient will be asked to provide written informed consent form and his/her eligibility for enrolment into the trial will be checked. Physical examination will be performed. An appointment will be made for the first MSNA measurement before kidney denervation.

Second visit: The first MSNA measurement will be performed. This visit will take approximately an hour.

Third visit:

This visit will take place at least 4 weeks after the kidney denervation procedure. We have chosen for four weeks because then this appointment can be combined with the visit for SIMPLICITY study. All medications will be continued during the whole study.

#### Intervention

There are no interventions in this study.

#### Study burden and risks

Microneurography: there are no risks associated with this procedure. Usually, nerve recordings cause minimal discomfort and negligible, transient after-effects, when studies are done by an experienced technician.

# Contacts

**Public** Academisch Medisch Centrum

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

This study is a substudy of a multi-center randomized trial called SIMPLICITY. All patients included in SIMPLICITY study may be included in this study.

## **Exclusion criteria**

No exclusion criteria

# Study design

## Design

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

#### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2010
Enrollment:	10
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	08-01-2010
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

ССМО

ID NL29033.041.09