Muscle Sympathetic Nerve Activity and Cardiovascular Organ Damage in Patients with Chronic Kidney Disease and Hypertension

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

Summary

ID

NL-OMON31233

Source
ToetsingOnline

Brief title
Sympathetic activity and cardiovascular organ damage

Condition

- Other condition
- Nephropathies

Synonym
Chronic kidney disease, Chronic Renal Disease

Health condition

Hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: onderzoek: door afd nefrologie en radiologie;UMC utrecht

Intervention

Keyword: Cardiovascular damage, Chronic Kidney Disease, Hypertension, Sympathetic nerve activity

Outcome measures

Primary outcome

-Primary endpoint: Left ventricular (LV) mass;

-Primary expected outcome: a proportional relation between MSNA and LV mass

Secondary outcome

-Secondary endpoints:

o Glomerular filtration rate (GFR);

o Ejection Fraction

-Secondary expected outcome:

o Decrease in GFR as compared to baseline

o Decrease in Ejection Fraction as compared to normal population

Study description

Background summary

Sympathetic hyperactivity is often present in chronic kidney disease (CKD) patients. Apart from the so called traditional risk factors, also risk factors more or less specific to CKD contribute in the pathogenesis of these problems. There is evidence that also independent of its effect on blood pressure, sympathetic hyperactivity is important in the pathogenesis of cardiovascular organ damage. Previously, we have shown that angiotensin converting enzyme inhibitors (ACEi) and angiotensin II receptor blockers (ARB) reduce but not normalize this sympathetic hyperactivity. We re-analysed the cohort of patients who were investigated in the past and subsequently treated according to present guidelines. Our results show that, despite of treatment, the unfavourable relation between sympathetic hyperactivity and clinical outcome still exists. In present project, we propose to investigate the relation between sympathetic activity and signs of cardiovascular (CV) organ damage in the patients who had had MSNA measurement previously.

The central hypothesis of this project is that sympathetic hyperactivity is of critical importance in the pathogenesis of CV organ damage in CKD patients.

Study objective

Our primary objective is to investigate if the previously found MSNA is related to the presence and severity of CV organ damage quantified as left ventricular mass, independent of other CV risk factors.

We hypothesize that despite of treatment previously assessed MSNA is still predictive for the presence of CV organ damage.

Secondary objective is the relation of MSNA to the presence of other signs of CV damage such as reduced left ventricular function and reduced GFR.

Study design

This is a follow-up study. We collect prospectively data on presence of CV organ damage, in particular LV mass and kidney function and relate these variables to MSNA data obtained in the past and with retrospectively collected data on various treatment aspects. The participants will be invited for a Magnetic Resonance Imaging (MRI) without contrast.

Materials:

Blood pressure measurement: Systolic and diastolic blood pressure will be measured at the arm with an automated and calibrated blood pressure device with the subject in supine position.

MRI-scan without contrast: Left ventricular mass and ejection fraction will be assessed using MRI without contrast.

Renal function: Plasma Renin Activity, GFR en serum creatinine will be measured as routin laboratory controls.

Study burden and risks

There are no risks associated with participation in this study. The magnetic field produced by MRI without contrast agent is harmless for the participants.

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 hypertension (i.e. using antihypertensive drugs and/or blood pressure >145/90mmHg when off medication) with stable chronic kidney disease

Exclusion criteria

Patients with clinically manifested cadiac history

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):	21-12-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	23-10-2007
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	NL16538.041.07