# The effect of Renal Denervation on Renal Flow in Humans

Published: 05-03-2013
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To investigate whether pRDN leads to a change in renal blood flow

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vascular hypertensive disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON39747

**Source**
ToetsingOnline

**Brief title**
Renal Flow after pRDN

### Condition

- Vascular hypertensive disorders

**Synonym**
high blood pressure, intrarenal flow

**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:** flow reserve, renal denervation

## Outcome measures

### Primary outcome

Primarily the effect of pRDN on renal blood flow, assessed by a change in

average peak flow velocity, both in baseline as well as hyperaemic conditions.

### Secondary outcome

The effect of pRDN on renal flow reserve (RFR), and hyperaemic microvascular

resistance (HMR).

# Study description

### Background summary

Although many studies have studied the effect and safety of pRDN, it remains unknown what the exact mechanism behind renal denervation is. Small animal studies have suggested an improvement of flow after pRDN in pigs experiments (presented at ACC 2012). It can be hypothesized that a difference in renal blood flow leads to an improved renal perfusion, and consequently a reduced BP. In the light of this ignorance, we wish to perform an observational study to investigate whether pRDN leads to a difference in renal blood flow after treatment with pRDN.

### Study objective

To investigate whether pRDN leads to a change in renal blood flow

### Study design

Monocentre, observational pilot study in 20 patients.

### Study burden and risks

The 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 slightly increased infection risk due to prolonged duration of the denervation.

# 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 has experienced a myocardial infarction, unstable angina pectoris, or a cerebrovascular accident within 6 months of the screening visit, or has widespread atherosclerosis, with documented intravascular thrombosis or unstable plaques.
4.Individual has any serious medical condition, which in the opinion of the investigator, may adversely affect the safety and/or effectiveness of the participant or the study (i.e., patients with clinically significant peripheral vascular disease, abdominal aortic aneurysm, bleeding disorders such as thrombocytopenia, haemophilia or significant anaemia).
5.Individual is pregnant, nursing or planning to be pregnant.
6.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

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-05-2013 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 05-03-2013 |
| 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 | NL42766.041.12 |