

The effect of Renal Denervation on Renal Flow in Humans

Published: 05-03-2013

Last updated: 24-04-2024

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

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

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX

NL

Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX

NL

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 $< 30 \text{ mL/min/1.73m}^2$, 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

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 07-05-2013

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

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