Functional Renal Hemodynamics in Patients with Renal Artery Stenosis 3

Published: 17-01-2020
Last updated: 10-04-2024

To study the clinical value of pressure and flow assessment for predicting treatment response to PTRA and validate the pressure gradient assessment by CFD in patients with available CT angiography.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON48149

Source
ToetsingOnline

Brief title
HERA 3 study

Condition

- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym
narrowing of the renal artery, Renovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: De nierstichting,Philips

Intervention

Keyword: Computational Fluid Dynamics, Hemodynamics, Pressure and flow measurements, Renal artery stenosis

Outcome measures

Primary outcome

Receiver operating characteristics for predicting ambulatory blood pressure

response after renal angioplasty by (1) the hyperemic pressure gradient, (2)

the hyperemic pressure gradient and the renal flow reserve.

Secondary outcome

The level of agreement between the CFD-predicted hyperemic pressure drop and

the invasively measured pressure drop.

Study description

Background summary

In patients with renal artery stenosis (RAS), pressure and flow measurements in the renal artery may help identify patients who will benefit from percutaneous transluminal renal angioplasty (PTRA). Based on the findings of the first HERA study and the ongoing HERA-2 study, pressure and flow measurements under dopamine infusion in the renal artery are feasible, safe and reproducible. Moreover, image-based computational fluid dynamics (CFD) using CT angiography may be able to non-invasively reproduce these pressure measurements, which can strongly increase the clinical applicability of functional assessment in this disease. CFD simulations have recently been validated and approved for deciding in which patients to perform a percutaneous coronary intervention. To date, no clinical validation of CFD simulations in the renal artery is available.

Study objective

To study the clinical value of pressure and flow assessment for predicting treatment response to PTRA and validate the pressure gradient assessment by CFD in patients with available CT angiography.

Study design

Single-center, cohort study with invasive measurements.

Study burden and risks

The burden of this study consists of exposure to an additional 8 ml of contrast medium for guide wire positioning, along with an intra-renal bolus of 30 µg/kg dopamine. The duration of the catheterization procedure is lengthened by an additional 30 minutes, and the study incus two extra hospital visits of 7,5 hours for renal clearance measurements. A total of 146 ml of blood is collected during renal clearance measuements. The intra-renal measurements and additional kidney clearance measurement incur a radiation burden of at most 4.8 mSv. Patients have no direct individual benefit by participating in the study, but their participation does contribute to a potentially improved treatment selection for future patients with the same disease.

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

Age > 18
Written informed consent
Clinical indication for percutaneous transluminal renal angioplasty
Clinically and hemodynamically stable
CT-angiogram or MR-angiogram of the renal arteries
Renography

Exclusion criteria

Known atrial fibrillation with irregular ventricular response rate
Increased risk for contrast nephropathy defined as presence of renal impairment (eGFR <30ml/min) according to the Guideline Safe Use of Contrast Media of the Radiology Society of the Netherlands (November 2017)
Women of child bearing age not on active birth control
Inability to sign an informed consent, due to any mental condition that renders the
subject unable to understand the nature, scope, and possible consequences of the trial or due to mental retardation or language barrier

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-08-2020

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	17-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL71172.018.19