Functional Renal Hemodynamics in Patients with and without Renal Artery Stenosis 2

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

Summary

ID

NL-OMON55815

Source
ToetsingOnline

Brief title
HeRA 2 Study

Condition

- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym
atherosclerotic renal artery stenosis, renovasculair disease, secundaire hypertensie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hemodynamics, Pressure and flow measurements, Renal artery stenosis

Outcome measures

Primary outcome

Dynamic range of renal blood flow, represented by the relative baseline flow, the ratio between the difference of baseline and minimal flow velocity and baseline flow velocity.

Secondary outcome

Renal flow reserve, relative minimal flow, renal fractional flow reserve, baseline and hyperemic renal stenosis resistance, baseline and hyperemic microvascular resistance, phase difference between pressure and flow in sympathetic band for autoregulation.

In patients where offline renal perfusion analysis is possible: renal perfusion as area under the curve of contrast density over time and the renal flow reserve computed by perfusion angiography.

Correlation of main study parameters with relevant clinical, biochemical and imaging parameters.

Study description

Background summary

In patients with atherosclerotic renal artery stenosis (RAS), combined intra-renal pressure and flow measurements allow a comprehensive evaluation of

macro- and microvascular renal disease, which may help to identify patients who will benefit from percutaneous transluminal renal angioplasty (PTRA). Based on the findings of the first HERA study, intra-renal pressure and flow measurements are feasible, safe and reproducible. Before we study the clinical utility of pressure-and flow guided renal revascularization, we first need to determine the physiological range of pressure and flow variations in the renal artery. This can be performed by measuring exercise-induced minimal flow next to dopamine-induced hyperemia. In addition, the relation of pressure and flow may also help us to assess renal autoregulation which is important for the maintenance of renal perfusion in patients with renovascular disease and chronic kidney insufficiency.

Study objective

The primary objective of this study is to assess the dynamic range of renal pressure and flow velocity under exercise induced minimal flow and dopamine induced hyperemia. Secondary objectives are to assess intra-individual variations in the range of pressure and flow and to assess renal autoregulation.

Study design

Single-center, cohort study with invasive measurements.

Study burden and risks

The burden of this study consists of exposure to an additional 30 ml of contrast medium for renal angiography and the placement of a 0.014-inch guide wire with pressure and flow sensors (Combowire, Philips-Volcano, San Diego, US) in one of the renal arteries. In addition, a renal hyperaemic response is induced by an intra-renal bolus of 30 *g·kg-1 dopamine. The duration of the catheterization procedure is lengthened by an additional 30 minutes. A total of 50 ml of blood is collected during catheterization. The risks of this study consist of the occurrence of contrast nephropathy, renal artery dissection and cholesterol embolization. These risks are considered very small as no catheter-based intervention takes place in the renal arteries. In the first HERA study that used a more extensive protocol with duplicate measurements to assess reproducibility, no adverse events occurred in the 39 patients who participated in that study.

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
Clinically and hemodynamically stable
Clinical indication for a coronary, renal, or peripheral vascular angiography with or without percutaneous intervention.

Exclusion criteria

Recent ST-segment elevation myocardial infarction (<6 weeks prior to enrolment)
Known cardiac arrhythmias
Known heart failure (NYHA class > II)
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:	Recruitment stopped
Start date (anticipated):	30-07-2019
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2021

Application type:	Amendment
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	NL68272.018.18