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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24285

Source
NTR

Brief title
HeRA 2 Study

Health condition

Renal artery stenosis, renovascular disease, hypertension, chronic kidney disease

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: In-kind support by Philips-Volcano for the measurement wires

Intervention

Outcome measures

Primary outcome

Dynamic range of renal blood flow, represented by the relative baseline flow (RBF), 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 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. 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 objective

We hypothesize that in general the relative base flow is less or equal then 20%.

Study design

-

Intervention

The study will compromise a series of intra-renal pressure and flow measurements that are consecutively performed at rest, during exercise induced minimal flow, and during hyperemia. The measurements will be performed following routine cardiac care or peripheral angiography/intervention by an experienced interventionalist. Minimal flow will be induced by

a static and dynamic handgrip test. Hyperemia will be induced by a slow bolus injection of dopamine 30 µg·kg-1 injected directly into the renal artery.

Contacts

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Eligibility criteria

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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2019
Enrollment:	16
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-08-2019
Application type:	First submission

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
NTR-new	NL7946
Other	METC AMC : METC 2018_305

Study results