Functional renal hemodynamics in patients with and without renal artery stenosis

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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-OMON47085

Source
ToetsingOnline

Brief title
HeRA Study

Condition

- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym
atherosclerotic renal artery stenosis, renal artery calcification

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 Measurement, Renal Artery Stenosis, Single Wire

Outcome measures

Primary outcome

To assess the feasibility and reproducibility of intravascular measurements of pressure and flow velocity in renal arteries and derived diagnostic parameters (hyperemic stenosis resistance, baseline and hyperemic microvascular resistance, renal flow reserve) in patients with a history of hypertension undergoing elective cardiac catheterization with pressure and flow measurements.

Secondary outcome

N/A

Study description

Background summary

Atherosclerosis consists of a chronic systemic inflammatory response in the walls of arteries, resulting in plaques within the arterial wall. In case of coronary artery and renal artery stenosis, these plaque lesions can result in cardiac angina and hypertension, respectively.
Treatment of these stenoses by percutaneous transluminal angioplasty and stent placement may lead to improvement in perfusion in affected arteries. However, the effect of these interventions in both heart and kidneys are variable.
Pressure and flow measurement is a technique used in cardiac catheterization to measure the significance of atherosclerotic lesions in coronary arteries. A pressure difference across a stenosis indicates the severity of the lesion.
This technique has proven to be a reliable parameter to determine the significance of an atherosclerotic plaque lesion in patients with coronary disease. At present current techniques are insufficient to identify patients with renal artery stenosis, who may benefit from PTA and stent placement. We believe that measurement of pressure and flow in renal arteries may identify

the culprit lesion in patients with renal artery stenosis. In the present study our aim is to assess the reproducibility of pressure and flow measurements in one of the renal arteries in patients undergoing elective cardiac catheterization.

Study objective

This study aims to investigate the feasibility and reproducibility of simultaneous pressure and flow measurements in the renal artery, and derived parameters in patients undergoing elective coronary pressure and flow measurements, at rest and during pharmacologically induced hyperaemia.

Study design

Cohort study with invasive measurements

Study burden and risks

Participants are exposed to an additional 30ml of contrast medium for renal angiography. The same 0.014-inch guide wire with pressure and flow sensors (Combowire, Volcano, San Diego, US) that is used to perform the elective coronary pressure and flow measurements is subsequently placed in one of the renal arteries and advanced, if present, past a stenosis. A renal hyperaemic response is induced by an intra-renal bolus of 50µg*kg-1 dopamine. This can be performed safely without any significant systemic effects on haemodynamics. The procedures as proposed are preformed twice. The duration of the coronary catheterization will be lengthened by 20 minutes. A total of 50ml of blood is collected during catheterization.
Renal pressure and flow measurements as proposed in this study may enable us to determine the hemodynamic functionality of a given renal artery stenosis and the viability of renal microvasculature. These factors, we believe, greatly determine the effectiveness of percutaneous transluminal angioplasty in renal artery stenosis, and may ultimately aid in selecting patients with unilateral or bilateral renal artery stenosis who will benefit from PTA with stent placement.

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

Subjects who have provided written informed consent
Subjects who are >=18 yrs and <=75 years of age
Subjects who are clinically stable
Subjects with an indication for coronary angiography, renal angiography or percutaneous transluminal renal angioplasty (PTRA)
Subjects who are willing and able to comply with all study procedures

Exclusion criteria

Acute coronary syndrome
Cardiac arrhythmias
Heart failure (NYHA class > II)
Severe valvular heart disease
Severe renal artery stenosis (>90 % diameter stenosis)
Severe renal impairment (eGFR <30ml/min) or clinical indication for prehydration according to the 2007 CBO Contrast induced nephropathy guidelines

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):	10-03-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	12-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	22-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Not approved

Date:	12-03-2014
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	NL40795.018.12