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

Gepubliceerd: 09-08-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24285

Bron
NTR

Verkorte titel
HeRA 2 Study

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: In-kind support by Philips-Volcano for the measurement wires

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age > 18
Written informed consent
Clinically and hemodynamically stable
Clinical indication for a coronary, renal, or peripheral vascular angiography with or without percutaneous intervention.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-04-2019
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7946
Ander register	METC AMC : METC 2018_305

Resultaten