Renal Functional Imaging for Non-invasive Evaluation and Diagnostics

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In this pilot study, we aim to validate MR-measurement of GFR to gold standard clearance measurements in subjects with a range of different GFRs: namely chronic kidney disease (CKD) patients, hypertensive patients and healthy subjects.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON45267

Source
ToetsingOnline

Brief title
ReFINED

Condition

- Other condition
- Nephropathies

Synonym
chronic kidney disease, loss of kidney function

Health condition

hypertensie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Functional MRI, Inulin clearance, Kidneys, Renal function

Outcome measures

Primary outcome

Agreement between GFR as measured with MRI and GFR as measured with inulin

clearance.

Secondary outcome

NA

Study description

Background summary

Currently, diagnostic possibilities in nephrology are limited, time-consuming or invasive. Therefore, there is an urgent need for additional non-invasive diagnostic tools. Renal functional Magnetic Resonance Imaging (fMRI) is a promising modality to fulfil this need. In contrast to computed tomography (CT), MRI is based on magnetic fields and makes no use of radiation. A validated MR technique to measure renal blood flow (RBF) already exists. Furthermore, a technique has been developed to measure single kidney glomerular filtration rate (skGFR) without the use of contrast agents. Of this, the glomerular filtration rate (GFR) of both kidney*s combined can be derived, a measure frequently used clinically.

Study objective

In this pilot study, we aim to validate MR-measurement of GFR to gold standard clearance measurements in subjects with a range of different GFRs: namely chronic kidney disease (CKD) patients, hypertensive patients and healthy subjects.

Study design

In all subjects, both an MRI examination consisting of measurement of skGFR and RBF and clearance measurements will be performed on the same study day.

Study burden and risks

Subjects are subjected to a one hour MRI scan in a clinical MRI scanner. There are no known risks associated with MRI, beside temporary dizziness and claustrophobia. No contrast is needed. For clearance measurements, inulin is used. Risks associated with this agent is negligible. Clearance measurements can be experienced as demanding due to their duration, the installation of two intravenous access sites, frequent blood and urine collection and infusions. Blood will be sampled via one of the two intravenous access sites (in total 33 mL), to prevent the need for repeated venipuncture.

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

- Subject is >= 18 years of age
- Subject agrees to have all study procedures performed, and is competent and willing to provide written, informed consent to participate in this clinical study;Exclusively for subjects in the CKD group:
- Subject has a GFR of 30-60 ml/min/1.73 m2 ;Exclusively for subjects in the hypertension group:
- Subject has a systolic blood pressure of >=140 mmHg and/or a diastolic blood pressure of >=90 mmHg based on average of 3 office blood pressure readings, or a 24-h ambulatory blood pressure of >=140 mmHg systolic and/or >=90 mmHg diastolic; or is on antihypertensive medication
- Subject has no treatable secondary cause of hypertension
- Subject has no medical record of impaired kidney function (as defined by a GFR <60 ml/min/1.73m2);Exclusively for healthy volunteers:
- Subject has no medical record of impaired kidney function (as defined by a GFR <60 ml/min/1.73m2)
- Subject has no medical record of hypertension (as defined by a systolic blood pressure of >=140 mmHg and/or a diastolic blood pressure of >=90; or the use of antihypertensive medication)
- Subject can be age matched within a range of ±5 years to one or more subjects in the CKD and hypertension groups

Exclusion criteria

- Subject has an allergy or intolerance to any of the agents used in the study
- Subject has any contraindications for MRI according to screening protocol radiology department UMCU
- Subject is pregnant, nursing or planning to be pregnant
- Subject has a known, unresolved history of drug use or alcohol dependency, lacks the ability to comprehend or follow instructions, or would be unlikely or unable to comply with study follow-up requirements
- Subject refuses to be informed of chance findings possibly relevant to their health
- Subject is currently being treated with drugs that cause salt retention (e.g., systemic corticosteroids and fludrocortisone);Exclusively for healthy volunteers and hypertensive subjects:
- Subject has no known renal disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-03-2020
Enrollment:	35
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-03-2018
Application type:	First submission
Review commission:	METC NedMec

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	NL61078.041.17