Arterial Wall Inflammation in Chronic Kidney Disease

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To assess the degree of arterial wall inflammation as measured by 18F-FDG-PET/CT in subjects with chronic kidney disease.

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

Summary

ID

NL-OMON42311

Source
ToetsingOnline

Brief title
FLAME-CKD

Condition

- Renal disorders (excl nephropathies)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arterial wall thickening, Atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: CVON Genius beurs

Intervention

Keyword: Arterial wall inflammation, Atherosclerosis, Chronic Kidney Disease

Outcome measures

Primary outcome

The main study parameter is the 18F-FDG -PET/CT measurements of arterial wall inflammation (target-to-background ratio) compared to healthy control subjects.

Secondary outcome

To assess the correlation between the degree of arterial wall inflammation as assessed with 18F-FDG -PET/CT and circulating markers of inflammation and renal failure.

Study description

Background summary

Reduced eGFR is associated with an increased risk of cardiovascular mortality, independent of traditional risk factors. As chronic kidney disease (CKD) affects approximately 8% of the population, this association causes a major public health burden. Over the last decades, the role of inflammation in the pathophysiology of atherosclerosis has become increasingly important, and CKD has been associated with an increased inflammatory state.

18F-FDG-PET/CT is a nuclear imaging technique which measures metabolic activity by labelling glucose with a PET tracer (18-fluor), and is used as a read-out for atherosclerotic plaque inflammation. This technique has been safely applied in subjects with CKD.

Study objective

To assess the degree of arterial wall inflammation as measured by 18F-FDG-PET/CT in subjects with chronic kidney disease.

Study design

This study is designed as a single center, observational study. After screening

for eligibility, all subjects will undergo cardiovascular risk assessment and laboratory testing. Thereafter, all subjects will undergo an 18F-FDG -PET/CT scan.

Study burden and risks

The results of this study contribute to our understanding of accelerated atherosclerosis in subjects with chronic renal disease, thereby contributing to risk stratification in individual patients and development of new anti-atherosclerotic treatment. Individual subjects will gain no direct benefit from this study.

The risk and burden of participating in this study is estimated to be low. Patients will visit the hospital on one occasion for a maximum of 2 hours, the exposure to radiation related to 18F-FDG PET/CT scan is 5.3 mSv in this study. 18F-FDG PET/CT have been safely applied in subjects with decreased renal function.

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

1. Aged 50 years or older
2. Chronic Kidney Disease stages 3 and 4 (eGFR: 15-60 ml min-1)

Exclusion criteria

1. Malignant diseases or any clinically significant medical condition that could interfere with the conduct of the study in the opinion of the investigator.
2. Standard contra-indications to 18F-FDG PET, and CT based on physicians experience and current practices: Claustrophobia, Metal in the body, as a result of e.g. osteosynthetic material, pacemaker implantation or artificial cardiac valves.
3. Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study.
4. Participation in a scientific study with radiation exposure in the year prior to inclusion.
5. Planned radiation exposure in the next year due to participation in a research project with radiation exposure or for clinical reasons.
6. Planned or expected diagnostic procedures with radiation exposure due to a medical condition
7. Clinical signs of acute infection and/or CRP>10
8. History of MI/Stroke or known coronary artery disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2014
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2014
Application type:	First submission
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	NL48486.018.14