

# Efficacy of statin therapy on arterial wall inflammation in patients with Chronic Kidney Disease

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to evaluate the anti-inflammatory effects of 3 months statin therapy on vessel wall inflammation by means of FDG PET/CT in patients with CKD

|                              |                                      |
|------------------------------|--------------------------------------|
| <b>Ethical review</b>        | Approved WMO                         |
| <b>Status</b>                | Recruitment stopped                  |
| <b>Health condition type</b> | Renal disorders (excl nephropathies) |
| <b>Study type</b>            | Interventional                       |

## Summary

### ID

NL-OMON45991

### Source

ToetsingOnline

### Brief title

FLAME-CKD 2

### 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:** cardiovascular risk, chronic kidney disease, inflammation, statin

## Outcome measures

### Primary outcome

Change in target-to-background ratio (TBR) in patients with CKD before and after statin therapy

### Secondary outcome

- Monocyte subtyping will be assessed by FACS analysis
- Monocyte expression of genes involved in inflammation
- Trans endothelial migration will be assessed according to standard procedures at Sanquin as described in van Buul et al (16).
- In vitro cytokine production will be assessed using isolated monocytes of subjects. Monocytes will be stimulated with LPS, assessing production of inflammatory cytokines (IL6, TNF\*)
- Epigenetic changes will be assessed by looking at H3K4 methylation at target genes assessed in the previous steps.

## Study description

### Background summary

Atherosclerosis is the main cause of cardiovascular disease. It is an progressive disease with an inflammatory component, characterized by the formation of plaques in the arterial wall. After a long asymptomatic period, patients with atherosclerosis can present with symptoms of impaired blood flow due to stenosis or with acute complications due to plaque rupture (e.g. myocardial infarction, ischemic stroke).

Subjects with chronic kidney disease (CKD) have an increased cardiovascular mortality and acute-phase inflammation. Recently, we observed that patients

with chronic kidney disease (CKD) have a significant increase of arterial wall inflammation compared with healthy controls matched for gender, age and BMI. A study by Tawakol et al shows significant and rapid, dose-dependent reductions in vessel wall FDG uptake, i.e. inflammation by use of statin therapy. Therefore, our aim is to evaluate the anti-inflammatory effect of statin therapy in patients with CKD and enhanced vessel wall inflammation. Eventually, additional treatment or improved treatment of patients, specifically aimed on the vessel wall inflammation may be justified to decrease mortality rates in patients with CKD.

### **Study objective**

to evaluate the anti-inflammatory effects of 3 months statin therapy on vessel wall inflammation by means of FDG PET/CT in patients with CKD

### **Study design**

This is a single centre intervention study. At baseline PET/CT measurements will be performed. After baseline imaging, all patients with CKD will be treated with statin therapy for 3 months, after which the PET/CT will be repeated. Patients who were included in the flame study will start immediately with statin treatment, since baseline imaging is already performed.

Intervention: All patients with CKD will receive statin therapy after baseline imaging. Statin therapy will consist of a once daily dosis of 40 mg Atorvastatine.

### **Intervention**

3 months treatment with atorvastatin 40 mg 1 tablet daily

### **Study burden and risks**

The study consists of 2 study visits and 1 scheduled telephonic appointment. Patients will undergo 2 x FDG PET/C scans and 2x venapuncture will be performed.

## **Contacts**

### **Public**

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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. CKD stages 3 and 4 (eGFR: 15-60 ml min<sup>-1</sup>)

### 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
3. Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study.
4. Planned radiation exposure in the next year due to participation in a research project with radiation exposure or for clinical reasons.
5. Clinical signs of acute infection and/or CRP>10
6. History of MI/Stroke or known coronary artery disease
7. Already receiving lipid lowering treatment

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-11-2016

Enrollment: 17

Type: Actual

### Medical products/devices used

Product type: Medicine

Brand name: lipitor

Generic name: atorvastatin

Registration: Yes - NL intended use

## Ethics review

Approved WMO

Date: 08-09-2016

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 10-04-2017

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                     |
|----------|------------------------|
| EudraCT  | EUCTR2016-000478-39-NL |
| CCMO     | NL56613.018.16         |

## Study results

|                   |            |
|-------------------|------------|
| Date completed:   | 02-09-2019 |
| Actual enrolment: | 14         |