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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22577

Source
Nationaal Trial Register

Brief title
FLAME-CKD 2

Health condition

chronic kidney disease stages 3 and 4, defined by a eGFR of 15-60 ml min

Sponsors and support

Primary sponsor: Academical Medical Center
Source(s) of monetary or material Support: This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 667837

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To assess differences in the innate immune system in patients with CKD before and after treatment with statins.

Study description

Background summary

This is a single centre intervention study. Our present study will consist of 17 patients with chronic kidney disease stages 3 and 4, defined by a eGFR of 15-60 ml min-1. The primary endpoint is the change in 18F-FDG target-to-background ratio (TBR) following 12 weeks of Atorvastatin 40 mg once daily.

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

3 months intevention

Intervention

Statin therapy will consist of a once daily dosis of 40 mg Atorvastatine for 3 months

Contacts

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Eligibility criteria

Inclusion criteria

1. Aged 50 years or older

2. CKD stages 3 and 4 (eGFR: 15-60 ml/min per 1.73m2)

3. Not receiving lipid lowering therapy

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

8. Treatment with dialysis or renal transplantation

9. Treatment with CYP3A4 inhibitors

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-11-2016
Enrollment:	17
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-12-2017
Application type:	First submission

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
NTR-new	NL6717
NTR-old	NTR6896
Other	METC AMC : 2016_093

Study results