Clinical and Biochemical correlates of 18-FDG-PET/CT detected atherosclerotic plaque inflammation.

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- To correlate clinical and biochemical cardiovascular risk factors to arterial wall 18-FDG uptake in large artery atherosclerotic lesions.- To correlate inflammatory markers to arterial wall 18-FDG uptake in large artery atherosclerotic lesions.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON34581

Source
ToetsingOnline

Brief title
Correlates of atherosclerotic plaque inflammation

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Divisie-I bv;project 1700

Intervention

Keyword: atherosclerosis, inflammation, PET/CT, plaque

Outcome measures

Primary outcome

Correlation coefficients between clinical and biochemical cardiovascular risk

factors and inflammatory markers on the one hand and plaque inflammation

(measured as TBR) on the other hand.

Secondary outcome

n.a.

Study description

Background summary

Non-infectious inflammation plays a major role in the development and rupture of atherosclerotic plaques. Atherosclerotic imaging traditionally focuses on structural abnormalities only. Hybrid imaging of both structural and functional abnormalities (inflammation) can be performed using positron emission tomography /computed tomography using 18-FDG as a radiotracer. Previous studies have shown increased arterial wall 18-FDG-uptake in symptomatic atherosclerotic lesions, and increased uptake appears to predict clinical CVD independent of structural abnormalities. Preliminary evidence suggests a relationship between established traditional cardiovascular risk factors and increased arterial wall 18-FDG-uptake. However, more data are needed to explore the determinants of arterial wall 18 FDG uptake. Inflammatory parameters for example, such as hsCRP and myeloperoxidase, may be associated with increased inflammation.

Study objective

- To correlate clinical and biochemical cardiovascular risk factors to arterial wall 18-FDG uptake in large artery atherosclerotic lesions.
- To correlate inflammatory markers to arterial wall 18-FDG uptake in large artery atherosclerotic lesions.

Study design

Patients are seen once at the clinical research unit of the department of internal medicine at the VU University Medical Center just prior to their scheduled PET/CT scan. During this visit a cardiovascular risk profile will be established by taking patient history, performing a brief physical examination and drawing blood samples. Bivariate correlation analyses will be performed between potential determinants of FDG uptake and the target to background ratio (TBR = measure of plaque inflammation) in separate arterial regions.
Patients will be contacted 6 months after scanning to be asked about the occurrence of cardiovascular events

Study burden and risks

Participating in this study will not lead to any increased risk or burden for patients. There is no benefit for individual patients. For now the only benefit is scientific.

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

Being scheduled for 18-FDG-PET/CT examination at the VU university medical center

Exclusion criteria

- The use of immunosuppressive or cytotoxic medication at or 1 month prior to the scan.
- Inability to understand or unwillingness to provide informed consent.
- Plasma glucose > 11 mmol/l at time of PET/CT-scan.
- Suspected vasculitis as indication for PET/CT.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-10-2010
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

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	NL32957.029.10