Developing diagnostic criteria for the differentiation between large vessel vasculitis and atherosclerosis using 18FDG-PET/CT

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To establish criteria that differentiate between large-vessel vasculitis and atherosclerosis as a cause of enhanced vascular 18-FDG uptake on 18-FDG-PET/CT.

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

Summary

ID

NL-OMON42061

Source
ToetsingOnline

Brief title
Vasculitis or Atherosclerosis on 18FDG-PET/CT / VAPC

Condition

- Other condition
- Vascular disorders NEC

Synonym
blood vessel calcification, blood vessel inflammation

Health condition

atherosclerose (bloedvataandoeningen)

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: 18FDG-PET/CT, Atherosclerosis, Vasculitis

Outcome measures

Primary outcome

We anticipate that criteria relating to 18-FDG uptake distribution and

intensity, and presence of calcium deposits on low-dose CT, will differentiate

between vasculitis and atherosclerosis.

Secondary outcome

Not applicable

Study description

Background summary

The introduction of 18-FDG-PET/CT has caused a sharp increase in the frequency of large-vessel vasculitis diagnoses. Arterial 18-FDG uptake may, however, also be caused by atherosclerosis. Several factors that may differentiate between these two entities have been suggested in literature. However, currently, no qualitative, let alone quantitative criteria to differentiate vasculitis from atherosclerosis have been formally studied and hence do not exist.

Study objective

To establish criteria that differentiate between large-vessel vasculitis and atherosclerosis as a cause of enhanced vascular 18-FDG uptake on 18-FDG-PET/CT.

Study design

A single centre (VUmc) observational cohort study.

The study project consists of 3 phases:
1. Diagnostic accuracy of routine clinical assessments of PET-CT images typical of atherosclerosis and vasculitis, respectively, without imposed assessment criteria
2. Development of image assessment criteria for distinguishing atherosclerosis and vasculitis
3. Observer variability and diagnostic accuracy of reading large-artery PET-CT images using developed criteria

The total duration of the study is 1.5 years.

Study burden and risks

For the patients of group I there are no additional burdens or risks

The patients of group II should undergo a 18-FDG-PET/CT scan for which one extra hospital visit is required and for which they must stop eating 6 hours before the scan. Because of the PET/CT scan the patients will receive a minimal radiation exposure and there is a risk of incidental findings,

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group I:
Patients with biopsy-proven giant cell arteritis with any type/degree of large-artery 18-FDG-uptake in the absence of clues pointing to severe atherosclerosis (history of cardiovascular disease or a >2-fold increased age-adjusted CVD risk. Patient scans will be retrieved from our database.;Group II:
Patients with severe atherosclerosis affecting at least the thoracic and/or abdominal- iliacal aorta and any type/degree of large-artery 18-FDG uptake. Patients >50 years of age with manifest atherosclerotic disease will be selected from the vascular surgery outpatient clinic.

Exclusion criteria

Group I:
Use of immunosuppressive drugs
Known cancer
Reluctance or inability to provide informed consent;Exclusion criteria for group II:
ESR >30 mmHg and/or CRP >10 mg/l
Myalgia in shoulder/pelvic regions (suggestive of PMR)
History of vasculitis or other type of systemic auto-immune disease
Use of immunosuppressive drugs
Reluctance or inability to provide informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	10-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2015
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
CCMO	NL49373.029.14