Detection of cardiac amyloidosis with 18F-florbetaben PET: a proof-of-principle study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON41377

Source
ToetsingOnline

Brief title
Detection of cardiac amyloidosis with 18F-florbetaben PET

Condition

- Myocardial disorders
- Cranial nerve disorders (excl neoplasms)

Synonym
Cardiac amyloidosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Amyloidosis, Heart, Imaging

Outcome measures

Primary outcome

The primary endpoint of this study will be demonstrating that PET-scintigraphy

with 18F-florbetaben is able to image cardiac amyloidosis.

Secondary outcome

The secondary endpoint is to demonstrate that patients with cardiac amyloidosis

have cerebral amyloid deposits.

Study description

Background summary

Cardiac amyloidosis is a diagnostic challenge. In patients with suspected cardiac amyloidosis and with a non-cardiac biopsy showing amyloid deposition, cardiac involvement has been defined by a consensus opinion from the 10th International Symposium on Amyloidosis as either a positive endomyocardial biopsy and/or increased left ventricular wall thickness in the absence of hypertension or other potential causes of true left ventricular hypertrophy. However, the gold standard remains a endomyocardial biopsy showing a positive Congo red-staining with characteristic green birefringence in polarized light. In two retrospective studies, 40 of 41 patients had a positive myocardial biopsy, suggesting that myocardial biopsy is highly sensitive in properly selected patients. Sensitivity of rectal biopsy in one series of 193 patients was 84 percent. The sensitivity of kidney, liver, and carpal-tunnel biopsies were all 90 percent or more in the same cohort. However, the sensitivity of non-target organ biopsies, for example subcutaneous fat is only 75 to 88% in patients with systemic amyloidosis. The risk of haemorrhage after biopsy of a clinically affected tissue, such as renal biopsy, is 1-2%. Myocardial biopsy should be done in experienced centres, but even then it can give complications like perforation or bleeding. On the other hand, early recognition of the severity of cardiac amyloidosis is important to determine the prognosis and thus to make decisions concerning ICD implantation or heart transplantation. Therefore, reliable early non-invasive detection of cardiac involvement is invaluable.

With the development of a new PET tracer, 18F-florbetaben, it may be possible to assess amyloidosis with PET.

Study objective

The aim of this *proof-of-principle* study is to demonstrate that 18F-florbetaben PET can detect amyloid deposition in the myocardium in patients with proven cardiac amyloidosis and excluded amyloid deposition in the myocardium of healthy subjects. Secondly, we want to study whether patients suffering from cardiac amyloidosis have an increased amyloid load detectable in the brain.

Study design

This is a non-randomized, single centre, observational study.

Study burden and risks

The amount of radioactivity that the participants are administered is within the international limits set for his subjects. It should be noted that a subject not often than once a year may be exposed to a radiation dose.

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

Cardiac amyloidosis:
1) Defined as histological proven by biopsy of the myocardium
2) or if not proven by myocardial biopsy the patient must fulfill all of the following criteria:
- Biopsy proven amyloidosis in another organ than the heart
- Left ventricular hypertrophy (> 12 mm) in combination with right ventricular hypertrophy (> 5 mm).
- Diastolic dysfunction and biatrial dilatation.
- Monoclonal protein and bone marrow plasmaceldyscrasie or transthyretin mutation

Exclusion criteria

Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	27-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2015
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	NL40225.018.12