Role of whole body C11-PiB in patients with systemic amyloidosis: a pilot study

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To evaluate if 11C-PiB is able to detect amyloid deposits in affected other organs and tissues in patients with systemic amyloidosis and to correlate the uptake of 11C-PiB in the different organs to laboratory parameters, biopsies and other imaging...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34619

Source
ToetsingOnline

Brief title
Whole body C11-PiB in patients with amyloidosis

Condition

- Other condition

Synonym
amyloidosis, protein deposit

Health condition

amyloidose (eiwitstapelingen) in diverse organen en weefsels

Research involving
Human

Sponsors and support

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

Intervention

Keyword: amyloidosis, C11-PiB, whole body scan

Outcome measures

Primary outcome

Uptake of 11C-PiB in organs known with amyloid depositions.

Secondary outcome

Not applicable.

Study description

Background summary

Amyloidosis is a disease characterized by deposition of amyloid in organs and tissues. For specific evaluation of systemic amyloidosis, serum amyloid P component (SAP) scintigraphy is extensively used. However for brain and cardiac involvement, 123I-SAP is not useful. In the brain, the PET tracer 11C-Pittsburg compound B (PiB) is used with good results for imaging amyloid in Alzheimers disease.

Study objective

To evaluate if 11C-PiB is able to detect amyloid deposits in affected other organs and tissues in patients with systemic amyloidosis and to correlate the uptake of 11C-PiB in the different organs to laboratory parameters, biopsies and other imaging studies.

Study design

A pilot study of 10 patients will be performed to evaluate if 11C-PiB is able to detect amyloid deposits in affected other organs and tissues. The 11C-PiB-PET scans will be evaluated qualitatively and quantitatively and correlated to other parameters. If 11C-PiB-PET scan is proved to be useful,

larger studies with more patients will be performed.

Study burden and risks

Risk of a bruise or hematoma because of the infuse.
No side-effects expected.
The effective radiation dose will be 3.4 mSv per patient.

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

Patients known with systemic amyloidosis with known amyloid deposits in various organs

Exclusion criteria

Patients < 18 years, pregnant or lactating women, and patients with claustrophobia

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL32567.042.10