Amyloid-PET as a diagnostic marker in daily practice.

Published: 18-12-2014
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To investigate in an unselected memory clinic sample, the clinical value of 18F]FBB PET in terms of1. change in diagnosis;2. change in level of confidence of diagnosis;3. impact on patient healthcare management.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON44936

Source
ToetsingOnline

Brief title
ABIDE-PET

Condition

- Structural brain disorders

Synonym
Alzheimer's disease, Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Piramal Imaging S.A.

Intervention

Keyword: Amyloid-PET.

Outcome measures

Primary outcome

The main outcome measure is the clinical value of [18F]FBB PET, which will be operationalized as follows. (i), the change in diagnosis, (ii) change in the level of confidence in the diagnosis, (iii) the impact on future patient management as measured using additional ancillary investigations, prescription of medication and use of health care.

In addition, patients who do not (yet) have dementia (i.e. subjective complaints, MCI), clinical progression to MCI or dementia during annual follow-up (based on follow-up visits to neurologist and neuropsychologist) will serve as additional outcome measure. Furthermore, in a subset of demented patients we will obtain clinical follow-up to examine the relation with rate of progression.

Secondary outcome

N.a.

Study description

Background summary

In a former study, we studied diagnostic impact of [11C]PIB-PET in a large group of memory clinic patients. We found that amyloid-PET has a large impact on diagnosis and the clinicians* confidence in the diagnosis.1 [11C]PIB-PET can only be used where an on-site cyclotron is available for production, hampering its widespread implementation. With the development of [18F]-tracers, which do not require on-site production and are therefore more suitable to be used by

local memory clinics, the question of the diagnostic value in an unselected patient sample becomes more urgent. In the former study, [11C]PIB-PET was performed in a selected sample. In the current project, we aim to take the next step by studying the diagnostic value of an F18 tracer, [18F]Florbetaben ([18F]FBB), in a large and unselected memory clinic sample.
We therefore aim to assess the added clinical value of amyloid-PET scan in a large and unselected population of patients visiting our memory clinic.

Study objective

To investigate in an unselected memory clinic sample, the clinical value of 18F]FBB PET in terms of
1. change in diagnosis;
2. change in level of confidence of diagnosis;
3. impact on patient healthcare management.

Study design

Prospective and longitudinal, observational study.

Study burden and risks

Risks associated with participation in this study are related to 1) radiation exposure; 2) idiosyncratic reaction to the tracer; 3) placement of intravenous catheter; 4) discomfort during scanning.

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

1) Patients of the VUmc Alzheimer Center with a written informed consent.;2) Patients of the UMC Utrecht who:
a) visited the Centre of Vascular Cognitive Impairment or
b) Parelsnoer participants.
And were diagnosed with mild cognitieve impairment and provided a written informed consent.

Exclusion criteria

Patients who
- are considered medically unstable (assessed by physician);
- require additional laboratory tests or workup between enrollment and completion of the [18F]FBB PET scan;
- are females of childbearing potential who are not surgically sterile, not refraining from sexual activity or not using reliable methods of contraception. Females of childbearing potential must not be pregnant or breast feeding at screening. Females must avoid becoming pregnant, and must agree to refrain from sexual activity or to use reliable contraceptive methods such as prescribed birth control or IUD for 24 hours following administration of [18F]FBB;
- are not able to give informed consent (personally or via authorized person) for whatever reason.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2015
Enrollment:	516
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Neuraceq
Generic name:	Florbetaben (18F)

Ethics review

Approved WMO Date:	18-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-04-2017
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
EudraCT	EUCTR2014-000562-21-NL
CCMO	NL50318.029.14