The ABIDE-PET study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON21592

Source
NTR

Brief title
ABIDE-PET

Health condition

Alzheimer's Disease, Mild Cognitive Impairment, PET, florbetaben, dementia

Sponsors and support

Primary sponsor: VU Medical Center.
Source(s) of monetary or material Support: VU Medical Center and Piramal Imaging.

Intervention

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.

Secondary outcome

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.

Study description

Background summary

SUMMARY

Rationale

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.

Primary 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 population: Unselected patient population of n=500 subjects visiting the memory clinic of the
VUmc Alzheimer center.

Intervention (if applicable): [18F]FBB PET scan.

Main study parameters/endpoints:

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.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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.

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

N.a.

Intervention

Florbetaben PET-scan.

Contacts

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Eligibility criteria

Inclusion criteria

All patients presenting at VUmc memory clinic will be invited to participate in the study.

Exclusion criteria

Patients who

- are mentally incompetent

- 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 for whatever reason.

Study design

Design

Intervention model: Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-01-2015
Application type:	First submission

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
NTR-new	NL4924
NTR-old	NTR5026
Other	NL50318.029.14 : 2014.483

Study results

Summary results
n.a.