The ABIDE-PET study.

Gepubliceerd: 05-01-2015 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON21592

Bron
NTR

Verkorte titel
ABIDE-PET

Aandoening

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

Ondersteuning

Primaire sponsor: VU Medical Center.
Overige ondersteuning: VU Medical Center and Piramal Imaging.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N.a.

Onderzoeksproduct en/of interventie

Florbetaben PET-scan.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Blindering: Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-01-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4924
NTR-old	NTR5026
Ander register	NL50318.029.14 : 2014.483

Resultaten

Samenvatting resultaten

n.a.