Dutch Flutemetamol Study

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Primary objective:1. To investigate the clinical value of [18F]Flutemetamol PET in memory clinic patients and especially those with suspicion of young onset dementia in terms ofa. change in (level of confidence of) diagnosis;b. impact on patient...

Ethical review	Approved WMO
Status	Completed
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON39989

Source
ToetsingOnline

Brief title
Dutch Flutemetamol Study

Condition

- Neurological disorders NEC

Synonym
Alzheimer's Disease, dementia of the Alzheimer type

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: Alzheimer's Disease, □-amyloid, Flutemetamol, Positron Emission Tomography (PET)

Outcome measures

Primary outcome

The main outcome measure is the clinical value of [18F]Flutemetamol PET, which can be subdivided into four outcome measures. First, the change in (the level of confidence in) the diagnosis as assessed by the clinician after the disclosure of the PET results will be measured. Secondly, the impact on future patient management as measured using additional ancillary investigations, prescription of medication and use of health care will be measured. Third, the diagnostic accuracy for final diagnosis defined by a consensus panel of clinicians at 2 years follow-up (used as a reference diagnosis) will be estimated. Fourth, cost-effectiveness will be assessed using questionnaires that enables quality of life and care related costs calculation.

Secondary outcome

The concordance of [18F]Flutemetamol PET with CSF markers (A* 1-42, total tau and p-tau 181) and MRI markers (atrophy medial temporal lobe) will be assessed by binary rating (e.g. *normal* or *abnormal*) for each of these measures. Furthermore, the prognostic value of [18F]Flutemetamol will be measured using (repeated) cognitive measures (Mini Mental State Examination (MMSE) and the Cambridge Cognitive Test (CAMCOG)) obtained at baseline and at 1 and 2 year follow-up.

Study description

Background summary

Neuropathologically, Alzheimer*s Disease (AD) is characterized by amyloid plaques and neurofibrillary tangles. Development of the positron emission tomography (PET) tracer [11C]Pittsburgh compound-B ([11C]PIB) has for the first time enabled the visualization of amyloid-beta (A*) in vivo, and evidence shows high sensitivity and specificity in separating AD from controls.
However, [11C]PIB-PET can only be used where an on-site cyclotron is available for production, hampering it*s widespread implementation. [18F]-tracers, which do not require on-site production are therefore more suitable to be used by many more centers and enable studying the discriminatory value in the diagnostic setting. Recently, [18F]Flutemetamol has become available for study.

Study objective

Primary objective:
1. To investigate the clinical value of [18F]Flutemetamol PET in memory clinic patients and especially those with suspicion of young onset dementia in terms of
a. change in (level of confidence of) diagnosis;
b. impact on patient healthcare management;
c. diagnostic accuracy of final diagnosis at 2 years follow-up;
d. cost-effectiveness.

Secondary objectives:
1. To assess the concordance of [18F]Flutemetamol PET with established biomarkers acquired from CSF (A* 1-42, total tau and p-tau 181) and MRI (atrophy medial temporal lobe);
2. To assess the prognostic value of [18F]Flutemetamol PET.

Study design

This is an observational open 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 an intra-venous catheter; 4) discomfort during scanning.

1) Administration of 185 MBq [18F]Flutemetamol will result in a whole body effective dose of 3.5 mSv according to the GE-067study (see IB Edition 6/ March 2012). For comparison, the natural background radiation dose in the Netherlands gives an annual dose of 2 - 2.5 mSv. Thus, the total radiation exposure of the total PET procedure is within an acceptable range of a yearly (unnatural) radiation exposure with a maximum of 10 mSv. In case of previous exposure to radioactivity, subjects will be eligible if the yearly cumulative dose due to exposure to radiation remains below 10 mSv.

2) Idiosyncratic reaction to the tracer
The injected mass of [18F]Flutemetamol PET used in this study is negligible. [18F]Flutemetamol PET is a radiotracer that have been used in humans. Side effects have never been reported at the tracer doses used in PET studies. A physician will be available during each injection of the radiotracer.

3) Intravenous cannulation
There is a very small risk of infection and bleeding associated with intravenous catheters, which are prevented by proper techniques.

4) Discomfort during scanning
It may be uncomfortable to lie motionless in the cameras (both PET and MRI) and it may cause some subjects to feel anxious. Subjects will be made acquainted with the surroundings beforehand. Our staff will be available to provide support, reduce anxiety, optimise the comfort of the subject and remove the subject from the scanner if requested.

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

- Written informed consent;
- age *80 years;
- weight >50 kg;
- Mini Mental State Examination score * 18.

Exclusion criteria

Patients who
- are considered medically unstable;
- require additional laboratory tests or workup between enrolment and completion of the PET scan;
- are receiving any investigational medications, or have participated in a trial with investigational medications within the last 30 days prior to the PET scan;
- have ever participated in an experimental study with an amyloid targeting agent (e.g. anti-amyloid immunotherapy, *-secretase or *-secretase inhibitor) unless it can be documented that the subject received only placebo during the course of the trial;
- 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 (negative serum *-hCG at the time of screening and negative urine *-hCG on the day of imaging) 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]Flutemetamol;
- are claustrophobic;
- have abnormalities on MRI, other than white matter changes or an incidental small lacunar lesion, which may affect visual reading of Flutemetamol PET.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-12-2012
Enrollment:	0
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]Flutemetamol Injection
Generic name:	[18F]Flutemetamol

Ethics review

Approved WMO Date:	18-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-05-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-08-2014
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

ID: 24675
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-002303-18-NL
CCMO	NL39995.029.12
OMON	NL-OMON24675