18F-Flutemetamol PET/MRI for detection of plaque vulnerability in atherosclerosis

Published: 03-11-2016
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To validate 18F-Flutemetamol PET in the evaluation of plaque vulnerability.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON47765

Source
ToetsingOnline

Brief title
PET/MRI and plaque vulnerability: Flutemetamol

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriosclerosis, atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Stichting de Weijerhorst

Intervention

Keyword: Amyloid, Atherosclerosis, Flutemetamol, PET/MRI

Outcome measures

Primary outcome

Tracer uptake in the carotid artery will be correlated to vulnerable plaque characteristics on MRI. In the 5-10 CEA patients, tracer uptake and MR imaging of different plaque characteristics will be validated with plaque histology of the surgically removed specimen.

Secondary outcome

Tracer uptake in the brain.

Tracer uptake in the coronary arteries.

Radiological characteristics of (early) dementia, as assessed with brain MRI.

Medication use.

Cognitive symptoms based on subjective complaints prior to hospitalization.

Study description

Background summary

18F-flutemetamol is a PET tracer with high affinity for amyloid beta (Abeta). This has been extensively studied in Alzheimer disease (AD) patients. However, Abeta seems not only to be involved in AD pathology, but also has a role in atherosclerosis, which might explain the remarkable similarities in risk factors between these two pathologies. In vitro studies suggest that a major part of this association is based on the ability of amyloid to lead to macrophage activation and hence inflammation. These data lead to the hypothesis that Abeta is associated with plaque vulnerability

Study objective

To validate 18F-Flutemetamol PET in the evaluation of plaque vulnerability.

Study design

A cross-sectional validation study.

Study burden and risks

For optimal MR imaging patients will be injected with a Gadolinium based contrast agent, which is a common procedure and associated with very low risk of complications. The PET tracer 18F-flutemetamol has been studied extensively and is currently used in patients with AD. Adverse events were not frequent and mainly mild. The radioactivity dose will be minimized.

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

Age 18 years and older (no maximum age)
Informed consent by signed informed consent form regarding this study
Either: Patients, who are scheduled for carotid endarterectomy (CEA)
Or: Patients who are not scheduled to undergo a CEA, but have experienced a TIA/CVA/amaurosis fugax within the last 14 days and at least a 30% stenosis of the symptomatic carotid artery as based on imaging.

Exclusion criteria

Severe cognitive impairment, neurological deficit or comorbidity causing the study to be too high a burden for the patient or disrupting patient*s co-operation with scan procedures.
Evident other causality for stroke (cardiac embolus, small vessel disease, carotid dissection or thrombogenic diathesis).
Pregnant women and nursing mothers.
Contra-indications for MRI.
*Relative contra-indications for MRI-contrast agent: GFR <30ml/min/1,73m2/Previous allergic reaction to MRI contrast agent.
Contra-indication Flutemetamol: Hypersensitivity to the active substance or to any of the excipients, severe liver dysfunction

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Vizamyl
Generic name:	18F-Flutemetamol

Ethics review

Approved WMO Date:	03-11-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-07-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-09-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2016-002911-16-NL
CCMO	NL58543.068.16