PET for Registration of Inflammation in the Vascular wall of Intracranial
 Aneurysms

Published: 06-07-2017
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To ascertain the hypothesis that T-cell inflammation in the vascular wall of an unruptured intracranial aneurysm can be accurately detected with 18F-IL2 PET (proof-of-concept).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON44673

Source
ToetsingOnline

Brief title
PRIVIA study

Condition

- Central nervous system vascular disorders

Synonym
Unruptured intracranial aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Inflammation, Intracranial Aneurysm, PET, Unruptured

Outcome measures

Primary outcome

Detection of inflammation by 18F-IL2 PET, related to the gold standard

(histopathology/molecular analysis).

Secondary outcome

Analysis of interobserver variability in 18F-IL2 PET interpretation.

Study description

Background summary

The University Medical Center Groningen is a tertiary referral center for neurovascular diseases, e.g. intracranial aneurysms. In the Netherlands, the prevalence of intracranial aneurysms is estimated between 4 and 6% of the general population. The vast majority of these aneurysms is asymptomatic, but a rupture results in a so-called subarachnoid hemorrhage (SAH). An SAH is a hazardous hemorrhagic stroke that causes severe morbidity and mortality in a high percentage of the cases. Since the peak incidence of SAH is in middle-aged people (40-60 years old), the social impact of a ruptured intracranial aneurysm is much higher than other types of stroke. Thus, although only a minority of the aneurysms becomes symptomatic, the consequences of a ruptured aneurysm are so disastrous that there is a great demand for an personalized test that indicates whether an intracranial aneurysms is prone to become symptomatic or not. In symptomatic aneurysms it has been shown that inflammation in the vascular wall, in particular T-cell invasion, plays an important role in the action of the rupture. The hypothesis is that the probability of rupture (SAH) can be estimated by screening for T cell inflammation in the vascular wall of unruptured aneurysms. The T cells can be detected non-invasively by means of molecular imaging. The specific PET tracer fluorine- 18 labeled interleukin-2 (18F-IL2) is ideal for this purpose. By combining the PET with MR Angiography, the inflammation can be demonstrated selectively in the vascular wall of an aneurysm.

Study objective

To ascertain the hypothesis that T-cell inflammation in the vascular wall of an unruptured intracranial aneurysm can be accurately detected with 18F-IL2 PET (proof-of-concept).

Study design

Observational (diagnostic) pilot-study.

Study burden and risks

The burden and risks associated with the participation in this study are very limited. The PET and MRI are performed during the hospital admission on the day before the surgical procedure and requires no extra site visits. Because of the MRA-examination a dose of intravenous gadolinium contrast medium is administered, for which the standard protocol requires that the eGFR (renal filtration capacity) is adequate, and this laboratory test is a standard procedure in the preoperative work-up. No other requirement for the study have to be met. The PET comes with a radiation exposure of 2.7 mSv.

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 year
* Presence of an unruptured intracranial aneurysm
* Standard of care decision to treat the aneurysm
* The aneurysm is surgically accessible
* Aneurysm wall sampling is deemed possible by the surgeon
* Written informed consent is obtained

Exclusion criteria

Technical impairments to perform the study
* Incapacity to lie in prone position for 60 minutes
* Aneurysm size smaller than PET detection rate (<7 mm)
* Physical restrictions, e.g. morbid obesity
* Claustrophobia
o Evidence of active infection requiring antibiotic therapy
o Pregnancy or lactation
o Renal insufficiency (estimated glomerular filtration rate < 60
ml/min/1.73 m2)
o Known allergy to gadolinium contrast agent
o Patients with pacemakers, defibrillators, other implanted electronic
devices, or possible metal particles
o Treatment with metformin
o Multiple myeloma (Kahlers disease)
o Waldenstrom macroglobulinemia
o Myasthenia gravis
o Pheochromocytoma
o Mastocytosis
o Thyroid cancer
o Planned thyroid scan

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):	25-01-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	28-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	27-08-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2017-002183-41-NL
CCMO	NL52624.042.17