Predictive value of Magnetic Resonance Imaging (MRI), positron emission tomography (PET), and microemboli detection for stroke

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Primary: To investigate whether high-resolution MRI, 18F-FDG PET, and microemboli detection, or a combination of these techniques, enable to identify patients in the 30-69% stenosis group with an increased stroke risk. Secondary: To compare the...

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

Summary

ID

NL-OMON31611

Source
ToetsingOnline

Brief title
Predictive value for stroke

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerotic plaques, hardening of the arteries

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: atherosclerosis, imaging, plaque, stroke

Outcome measures

Primary outcome

Primary endpoint is ipsilateral recurrent ischemic stroke alone.

Secondary outcome

Secondary endpoints are the combined endpoint of ipsilateral ischemic stroke and ipsilateral TIA, and the combined endpoint of ipsilateral ischemic stroke, ipsilateral TIA, and ipsilateral silent infarct as detected on brain MRI.

Another secondary endpoint is the influence of patient positioning in the MRI scanner on results of plaque morphology and composition analyses.

Study description

Background summary

Patients with a moderate to severe carotid atherosclerotic plaque are at risk for stroke and this risk increases with increasing degree of stenosis. Subsequently, clinical trials showed that carotid endarterectomy in symptomatic patients with a carotid artery stenosis of 70-99% is highly beneficial, whereas the beneficial effect of surgery in patients with a 50-69% stenosis is not yet clear. The risk of a major stroke in the latter group is about 10% in the first year after symptoms, while the risk of a major stroke or surgical death within 30 days of surgery is about 7% (ECST trial). A clear beneficial effect of surgery in the 30-69% stenosis group might be found in a sub-group of patients whom are at greater risk for stroke after a TIA or minor stroke. Definition of this sub-group might be achieved by plaque characterization, since rupture of a vulnerable plaque is the main cause of stroke due to carotid artery stenosis. Important aspects of vulnerable plaques are a large lipid/necrotic core, inflammation, and embolization. Recently, we have shown that we can quantify these different aspects of plaque vulnerability in vivo: the size of the lipid/necrotic core with high-resolution MRI, the presence of inflammation with

18F-FDG PET, and the amount of microembolization with transcranial doppler ultrasound. The novel approach of the present project is to investigate whether one or a combination of the above mentioned imaging techniques enable to define patients in the 30-69% stenosis group with an increased risk to develop stroke. Future studies could then investigate whether these patients will profit from carotid endarterectomy or stenting.
To achieve this objective, we aim to image 263 symptomatic patients with a 30-69% carotid stenosis with high-resolution MRI, 18F-FDG PET, and microemboli detection with transcranial Doppler ultrasound. The patients will be followed up for a period of at least one year. The imaging findings will be correlated with clinical end-points (TIAs, minor/major stroke, silent infarct as detected as a change on FLAIR MRI after one year).
In summary, we expect that this project will provide an unique dataset which will show that high-resolution MRI, 18F-FDG PET, and microembolic detection, or a combination of these techniques, enable the definition of a sub-group of patients in the symptomatic 30-69% stenosis group with an increased stroke risk. Future studies will then be warranted to investigate whether these patients will profit from carotid endarterectomy or stenting.

Study objective

Primary:
To investigate whether high-resolution MRI, 18F-FDG PET, and microemboli detection, or a combination of these techniques, enable to identify patients in the 30-69% stenosis group with an increased stroke risk.
Secondary:
To compare the capabilities of high-resolution MRI, 18F-FDG PET, and microemboli detection concerning its abilities to define patients in the 30-69% stenosis group at increased risk for stroke. To assess the influence of patient positioning in the MRI scanner on results of plaque morphology and composition analyses (assessment of scan reproducibility). Assessment of scan reproducibility will be executed in 15 patients with an asymptomatic carotid artery stenosis.

Study design

Prospective study

Study burden and risks

Patients need to come to the hospital at inclusion, and will then undergo clinical assessment, an MRI examination (one hour), an 18F-FDG PET examination (1.5 hours) and microemboli detection with transcranial Doppler ultrasound (one hour).
After three months, after one year, and then yearly until the end of the study in 2011, the patients will come back to the hospital for clinical assessment.

Patients will also undergo an MRI examination after one-year follow-up.
Patients will undergo emboli detection with transcranial Doppler ultrasound at time of inclusion.
To assess the influence of patient positioning in the MRI scanner on results of plaque morphology and composition analyses, 15 patients with an asymptomatic carotid artery stenosis will undergo two MRI scans of the carotid artery. The second MRI scan will be obtained on a different day than the first MRI scan.
Patients with contra-indications for MRI, such as pace-makers, metal implants, vessel clips, or metal splinters in the eye will be excluded from the study.
The side-effects of the MRI contrast agent (Gd-DTPA) are rare and are amongst others, headache, nausea, itching, and the appearance of rash. In severe cases an allergic reaction and shock could occur. In most cases side-effects occur immediately after contrast injection, and therefore patients will remain in the hospital for 30 minutes after injection. The administration of the contrast agents is relatively safe and side-effects are rare.
Patients need to be sober at least six hours before PET scanning. Drinking of water and use
of medication is allowed.
Diabetic patients using oral medication:
-PET scanning before 14.00 pm: no breakfast, no medication
-PET scanning after 14.00 pm: breakfast before 8.00 am and normal use of medication.
Subsequently no more eating before scanning.
Insulin-dependent diabetic patients:
-PET scanning before 11.00 pm: no breakfast, no insulin injections
-PET scanning after 11.30: no breakfast, half of the normal insulin dose
-PET scanning after 14.00 m: breakfast before 8.00 am and normal morning insulin injection. Subsequently no more eating and no more insulin injections before scanning.
A PET/CT examination exposes a patient to an effective dose of approximately 8.5 mSv. The administration of 18F-FDG does not cause any adverse affects.

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

Patients with neurological symptoms due to ischemia in the carotid artery territory and with a carotid stenosis between 30% and 69% as detected by US will be included (n<=263)
Patients with an asymptomatic carotid stenosis (detected by US) (n<=15)

Exclusion criteria

-Patients with evident other cause of neurological symptoms than carotid stenosis.
-Patients that are already scheduled for carotid endarterectomy or stenting
-Patients that are already scheduled for an intervention that is associated with embolization.
-Severe co-morbidity, amaorosis Fugax, dementia, or pregnancy.
-Standard contra-indications for MRI (ferromagnetic implants such as pacemakers and other implanted electrical devices, metallic fragments in the eyes, surgical vessel clips, claustrophobia, documented allergy to contrast media etc).

Study design

Design

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

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2007
Enrollment:	278
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-06-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-08-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-09-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-10-2008
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
CCMO	NL16838.068.07