Atherosclerotic Carotid Plaque components correlated with Cerebral Damage at 7T

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Correlate plaque characteristics, determined on high resolution 7 Tesla MRI, with cerebral damage ((clinically silent) cerebral (micro) infarcts or bleeds), also seen on 7 Tesla MRI. As gold standard histology of the plaques will be obtained

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON34389

Source
ToetsingOnline

Brief title
PlaCD-7T

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, narrowing of the artery

Research involving
Human

Sponsors and support

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

Hartstichting

Intervention

Keyword: atherosclerosis, carotid arteries, cerebral damage, high resolution MRI

Outcome measures

Primary outcome

Specific plaque components (e.g. intra-plaque hemorrhage, neovasculature)

correlated with cerebral damage (micro-infarcts, micro bleeds) as seen on the 7

Tesla MRI images.

Secondary outcome

not applicable

Study description

Background summary

Embolisms, caused by (a) (ruptured) atherosclerotic plaque(s) in the carotid artery, can cause a TIA (Transient Ischemic Attack) or an ischemic stroke. Patients undergo a carotid endarterectomy for removal of these atherosclerotic lesions. The relation between the composition of the atherosclerotic plaque and 1) pre- and postoperative embolisms and 2) (recurrent) infarcts after surgery, were investigated in the Athero-Express study1. We found that patients with a fibrotic plaque had a lower risk for recurrent TIA or stroke than patient groups with a more lipid-rich plaque. Patients with a more inflamed plaque showed more embolisations (measured with Trans Cranial Doppler (TCD)). In addition, a high ration of neovasculature with intra plaque bleeding was a strong predictor for cardiovascular events throughout the whole body. Thus, the classically defined measures for plaque vulnerability (plaque bleeding, large lipid lakes and local inflammation) were all related with adverse outcomes peri-operatively as well as during follow up.

Recently, a 7 Tesla human MRI (Magnetic Resonance Imaging) scanner became available in the University Medical Center Utrecht (UMCU). This new technique creates the possibility to visualize carotid artery plaques using high resolution in vivo MRI and to correlate specific plaque components with

cerebral damage in humans.

Study objective

Correlate plaque characteristics, determined on high resolution 7 Tesla MRI, with cerebral damage ((clinically silent) cerebral (micro) infarcts or bleeds), also seen on 7 Tesla MRI. As gold standard histology of the plaques will be obtained

Study design

Patients scheduled for an endarterectomy of (one of) the carotid arteries are included via the vascular surgeon. These patients
have had a TIA or stroke, or are asymptomatic with a partially occluded carotid artery.(>70% stenosis)
About one day before surgery the patients are scheduled for an MRI scan of the head/neck area in the 7 Tesla MRI scanner. During this MRI scan the brain will be evaluated for micro infarct/bleeding damage. In the neck area, several MR images with several weightings will be aqcuired for plaque visualization and characterization. This will take approximately 75 minutes (including preparation of the patient). The biggest area of the plaque (culprit lesion) will be located at a certain distance from the carotid bifurcation. During the operation the plaque is excised and immediately processed. The segment with the biggest plaque (culprit lesion) is located and fixated in formalin for histological analysis. This segment is cut and stained for presence of: collagen, macrophages, smooth muscle cells, lipids, thrombus and endothelium (microvessels(neovasculature)). (Athero-Express studie) Additionally, several other segments will be fixated in formalin and subsequently stained. (approximately 50% of the plaque will be available for histology)

Study burden and risks

Nearly negligible risks, only the gadolinium injection could lead to rare side-effects, but by following the exclusion criteria very strictly this will be minimized.

Contacts

Public
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
NL

Scientific
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Selected for CEA based on (symptomatic or asymptomatic) carotid stenosis (>70%)
• Participation in Athero-Express study
• Adults and of sound mind

Exclusion criteria

• Patients with a physical handicap (immobility)
• Patients without informed consent
• Allergic reaction to gadolinium in the past
• Impaired renal function (severe renal insufficiency, GFR < 30ml/min/1,73m2; or nephrogenic systemic fibrosis/nephrogenic fibrosing nephropathy (NSF/NFD))
• Impossibility to undergo 7T MRI (claustrophobia, non-removable metal objects in the body)

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):	25-05-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32071.041.10