

In vivo human carotid artery atherosclerotic plaque characterization with high-resolution MRI at 3 and 7T

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Primary goal: To investigate whether specific plaque characteristics are associated with ischemic lesions, especially (clinically silent) cerebral micro-infarcts, we will perform preoperative high resolution 3 and 7 Tesla MR plaque imaging in...

Ethical review	Not approved
Status	Will not start
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON33964

Source

ToetsingOnline

Brief title

MRI 3T and 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

Hartstsichting

Intervention

Keyword: atherosclerosis, carotid arteries, high-resolution MRI

Outcome measures

Primary outcome

Number of micro vascular micro infarcts in the perfusion area of the carotid artery associated with specific plaque characteristics.

To visualize plaque characteristics that have been associated with micro-embolisms and post-operative stroke with high-resolution MRI (3 Tesla and 7 Tesla).

Therefore we will mainly look at microvessels (neovasculature) and lipid rich plaques

Secondary outcome

To visualize all plaque characteristics identified on histology and compare them with the high-resolution MR images (3 Tesla and 7 Tesla).

golden standard will be the histology

Comparison of pre- and post operative MR scan aimed at the perfusionstate of the brain. (Evaluate whether the operation improved perfusion in the brain) and whether specific components are related to the perfusion state/recovery of perfusion state.

Study description

Background summary

Embolisms, caused by (a) (ruptured) atherosclerotic plaque(s) in the carotid artery, can cause a TIA or a stroke. Patients will 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) repeated infarcts after surgery, were investigated in the Athero-Express study. We found that patients with a fibrotic plaque had a lower risk for repeated 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 number of neovasculature with intraplaque 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 follow up. Recently, a 7T human MR scanner became available in Utrecht, creating the possibility to visualize the carotid artery plaques with a high resolution in vivo MRI in humans. For comparison with a standard, the 3T human MRI scanner will also be used in half of the patients. In this single center prospective study, 84 patients (42 per group) with stenosis of one the carotid arteries and included in the athero-express bio bank will be included in this study. These patients will be recruited from the department of vascular surgery of the UMCU. Therefore our main question is to investigate if particular plaque characteristics are associated with clinically silent cerebral micro-infarcts. Therefore we will use histology as a golden standard. Our secondary aim is to visualize plaque characteristics, associated with micro-embolism and post-operative stroke, by high resolution MRI. Additionally, we want to visualize the perfusion state of the brain pre- and postoperatively to see what the influence is of the revascularisation of the brain. With this data we will be able to visualise the carotid artery vessel wall and obtain information of the composition of the plaque and the consequences in the brain. Additionally, with the brain images we can make statements about function of the brain and its perfusion state pre-operatively and after revascularisation. Thereby we can provide a basic understanding of the possible consequences of atherosclerosis of the carotid artery for the brain.

Study objective

Primary goal:

To investigate whether specific plaque characteristics are associated with ischemic lesions, especially (clinically silent) cerebral micro-infarcts, we will perform preoperative high resolution 3 and 7 Tesla MR plaque imaging in patients undergoing CEA, and correlate our results with ischemic lesions seen on follow-up (post-operative) MRI. As golden standard histology of the plaques will be obtained.

Secondary goal:

To visualize plaque characteristics which have been associated with micro-embolism and post-operative stroke with high-resolution 3 and 7 Tesla MRI, and compare these results, so as to obtain knowledge regarding the full use of MR imaging for determination of plaque composition.

Study design

Patients scheduled for an endarterectomy of (one of) the carotid arteries are included via the vascular surgeon. These are patients who have had a TIA or stroke, or asymptomatic patients with a partially occluded carotid artery.($>70\%$ stenosis)

1 day before surgery the patients are scheduled for an MRI scan of the head/neck area in the 3T or 7T (patients are randomly assigned to a group). During this MR scan the brain will be evaluated for micro infarct damage, as a marker for embolisms. In the neck area, several MR images with several weightings will be acquired for plaque visualization and characterization. This will take 1 hour (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 surgery the number of embolisms will be measured with TCD. During the operation the plaque is removed 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)
During a follow-up appointment with the surgeon (3 months after operation) a second MRI scan will be made of the brain, to evaluate the results of the operation and correlate with specific plaque components.

Study burden and risks

nearly negligible risks, only the gadolinium injection could lead to rare side-effects, but by following exclusion criteria very strictly

this will be as minimal as possible.

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

- * Selected for CEA based on (symptomatic or asymptomatic) carotid stenosis (>70%)
- * Participation in Athero-Express study
- * 18 years or older and of sound mind
- * Male or female

Exclusion criteria

- * Patients with a physical handicap (immobility)
- * Patients with no 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 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: Will not start

Enrollment: 84

Type: Anticipated

Ethics review

Not approved

Date: 17-02-2010

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	NL26366.041.09