Serial CT Angiography of atherosclerotic carotid plaque:determinants and prognosis of change in volume, composition and morphology

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1) To assess the the natural course of atherosclerotic disease in the carotid artery. 2) to evaluate whether a change in plaque volume, composition and morphology can be predicted based on risk factor profiles, baseline plaque status and shear...

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

Summary

ID

NL-OMON33613

Source
ToetsingOnline

Brief title
serial CTA of atherosclerotic plaque

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: atherosclerotic plaque, carotid artery, CTA

Outcome measures

Primary outcome

Change in atherosclerotic plaque volume, plaque composition and plaque

morphology in the carotid artery

Secondary outcome

1) Recurrent ipsilateral cerebrovascular event.

2) Ischemic stroke, myocardial infarction or vascular death

Study description

Background summary

It has been recognized that atherosclerotic plaque composition and morphology could be much more important than luminal stenosis for the development of acute neurovascular events: plaques consisting of a necrotic core covered by a thin fibrous cap are prone to rupture leading to thrombo-embolic events. Despite this concept, not much is known about the natural course of atherosclerotic disease in the carotid arteries.
In this project we will evaluate atherosclerotic carotid plaque features (plaque volume, plaque composition, plaque morphology, shear stress) with MDCTA

Study objective

1) To assess the the natural course of atherosclerotic disease in the carotid artery.
2) to evaluate whether a change in plaque volume, composition and morphology can be predicted based on risk factor profiles, baseline plaque status and shear stress and
3) To assess the predictive value of atherosclerotic plaque features (both baseline and changes) for risk of recurrent ipsilateral stroke?

Study design

Observational prospective study

Study burden and risks

In this study an extra MDCTA of the carotid artery is performed. Participants have to visit the hospital for this examination. An extra MDCTA requires additional ionizing radiation, which is within the international acceptable limits. MDCTA requires injection of contrast agents. This agents can provoke an allergic reaction and a decrease in renal function. In persons with a higher risk for renal insufficiency, a recent renal function has to be available.
During follow-up, the participants will be contacted once a year for a questionnaire which will take 15 minutes.
Benefits: There is no individual benefit. In case a carotid atherosclerotic stenosis has increased during follow-up to more than 70%, participants will be referred to a neurologist to discuss an intervention (surgery or stent placement).

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 cerebrovascular symptoms (amaurosis fugax, hemispheric TIA or minor stroke (Rankin < 3)) who had visited the department of Neurology. The neurologist examined the patient and decided whether the neurological symptoms can be considered to be caused by cerebral ischemia
- Patients had undergone MDCTA of the carotid arteries
- the presence of atherosclerotic disease in the carotid artery as seen on MDCTA.
- signed Informed consent

Exclusion criteria

·contrast material allergy
·renal insufficiency defined as eGFR <= 60 mL/min
·no informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2008
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	19-09-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-06-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL24449.078.08