Validation of CT Angiography and/or Magnetic Resonance Imaging markers for characterization and quantification of atherosclerosis in the carotid arteries by comparison with surgical specimens.

Published: 19-07-2018
Last updated: 11-04-2024

CT Angiography and MRI could provide information on lumen, vessel flow and/or plaque composition and morphology.1) Validation of CT angiography and/or MRI markers to identify the different components of the atherosclerotic plaque in the carotid...

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

Summary

ID

NL-OMON46530

Source
ToetsingOnline

Brief title
Carotid imaging.

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: Ministerie van OC&W

Intervention

Keyword: Angiography, atherosclerosis, carotid arteries, characterization and quantification

Outcome measures

Primary outcome

1) The accuracy of CT Angiography and/or MRI imaging markers of vessel lumen,

arterial flow and plaque composition to characterize

atherosclerotic plaque in the carotid arteries.

2) The accuracy of CT Angiography and/or MRI to quantify plaque volume and the

volume of the different plaque components.

3) Determinants: blood flow parameters. Outcome: to link blood flow parameters

to plaque composition and morphology

Secondary outcome

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Study description

Background summary

Atherosclerosis is a systemic disease that may silently affect the entire arterial tree. Frequently the initial clinical manifestation is stroke, myocardial infarction or sudden death. Stroke is the third most important cause of death in the Western world and the leading cause of permanent disability. Atherosclerotic disease in the carotid bifurcation is in 20-30% of the cases responsible for ischemic stroke. Since the further understanding of the pathological mechanism of atherosclerosis advances are being made in imaging this prevalent disease.
Histopathological studies have shown that the majority of myocardial

infarctions and stroke are due to an atherosclerotic plaque that erodes or ruptures generating a thromboembolic event at the site or downstream of the disrupted plaque. Interestingly the majority is mildly-to-moderately stenosed.

Cerebrovascular accidents like transient ischemic attack (TIA) and stroke are related to the size of the stenosis in the internal carotid artery, in symptomatic and asymptomatic patients (2-4). However in the past decade, it has been recognized that plaque vulnerability is much more important than plaque size for the development of acute events (5). The recognition of the role of the vulnerable plaque in the development of cardiovascular events provides a novel opportunity for improved risk assessment.

In the carotid vasculature, high risk or symptomatic plaques are those with a thin-fibrous cap, intraplaque inflammation or hemorrhage, and a lipid-rich necrotic core (LRNC). Ultrasound (US) and Computed tomography angiography (CTA) have established themselves as accurate modalities to assess the presence of atherosclerotic disease in the carotid bifurcation and grade the severity of stenosis (6). In addition, due to its inherent superior contrast resolution, multi-sequence MRI has the potential to identify and measure plaque structure in symptomatic subjects (lipid, haemorrhage, fibrotic tissue and calcium) in the carotid arteries and to quantify plaque volume and volume of different components (7-10). LRNC, as assessed with MRI, is related to the presence and extent of ischemic cerebral lesions 11. Contrast-enhanced plaque imaging improves the differentiation of the LRNC from fibrous tissue12-13. In addition MR images obtained during administration of contrast material can be used to quantify degree of plaque inflammation. Our aim in this study is to prove the ability of CT and/or MRI to image the vessel lumen, to assess bloodflow parameters, different plaque components and plaque morphology of an atherosclerotic plaque in the carotid arteries. In that case CT and/or MRI could provide information on plaque vulnerability and the risk of future events. It could influence therapeutic decisions. Moreover, development of atherosclerosis can be studied by relating blood flow parameters to plaque morphology and composition.

The study will be embedded in the Erasmus MC, a single center observational diagnostic study among 150 patients with acute symptomatic stenosis in the carotid arteries aged 18 years and older. All patients are planned for carotid endarterectomy (CEA) at the ErasmusMC. This population who will undergo a surgical operation is chosen for the reason that it will be possible to relate the CT or MRI scan with the removed carotid atherosclerotic plaque (gold standard).

Study objective

CT Angiography and MRI could provide information on lumen, vessel flow and/or plaque composition and morphology.

1) Validation of CT angiography and/or MRI markers to identify the different components of the atherosclerotic plaque in the carotid arteries by comparison with histologic specimens.
2) Evaluation of plaque development by relating MRI derived flow parameters to plaque composition and morphology on histology, and by relating plaque composition to plaque morphology

Study design

A single center observational diagnostic study.

Study burden and risks

There are no risks associated with participation in this study. The total burden of this study is one MRI examination in patients who are hospitalized for a CEA.

The side effects of the MRI contrast agent (Gadobutrol) are rare and are amongst others nausea (0.25%), vomiting (0.05%), urticaria (0.04%), feeling of warmth, tachycardia, wheals (for each 0.03%), dizziness, itching, vasodilatation, itchy throat (for each 0.02%) and cough, dyspnea, flushing, hives, generalized itching, oral dryness, facial redness, sensation of heat, skin disorder and aggravated nausea (for each, 0.01%)1.

Out of 14 299 patients, two serious ADRs occurred (0.01%), which were considered by the treating physician to be probable associated with the administration of adobutrol;
One patient had a severe anaphylactic reaction and the other presented with itching and swelling in the throat.

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 with a renal clearance (eGFR) of less than 30 mL/min will not receive the MR contrast agent. There are no other test, examinations or questionnaires.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 210

Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 210
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients with cerebrovascular symptoms (TIA, minor stroke) in the last six months
* CTA of the carotid arteries (at the Erasmus Medical Center or referring centre) during the last 2
months (CTA is performed for clinical work-up)
* Scheduled endarterectomy of a carotid artery
* Signed informed consent
* At least 18 years old
* Patients who have a documented allergy to MRI contrast media are eligible for MRI, but will not
undergo a contrast-enhanced scan. Patients with a renal clearance (eGFR) <30 ml/minute are eligible for MRI, but will not undergo contrast-enhanced MRI.

Exclusion criteria

* Woman who are pregnant or lactating
* Patients who are hemodynamically unstable
* Having any physical or mental status that interferes with the informed consent procedure
* Not being able to remain lying down for at least 40-45 min (e.g. patients with unstable

angina, dyspnea at rest, severe pain at rest, severe back pain)
* Contraindications for MRI (e.g. claustrophobia)
* Metal chip in the ocular bulb identified on X-ray (If a patient affirms to ever have had a metal chip in his eyeball an X-ray will be made to check if it is still present)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	19-07-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2020
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	NL65456.078.18