# Contrast-enhanced ultrasound and magnetic resonance imaging for the evaluation of neovascularisation in carotid artery plaques

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

## Summary

### ID

NL-OMON31966

**Source**
ToetsingOnline

**Brief title**
CE-US and MRI: evaluating plaque neovascularisation

### Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
arteriosclerosis, Atherosclerosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Bracco Imaging SpA;Milano;Italy,Bracco-Byk

## Intervention

**Keyword:** Atherosclerosis, Contrast-enhanced ultrasound, Magnetic resonance imaging, Neovascularisation

## Outcome measures

### Primary outcome

The accuracy of contrast-enhanced ultrasound and MRI in depicting

neovascluarisation in a carotid artery plaque.

### Secondary outcome

Not applicable.

# Study description

### Background summary

The process of atherosclerosis usually starts at young age. Gradually, in blood vessels lesion with lesions with composed of fat, smooth muscle cells and connective tissue arise. Eventually, these so-called plaques can cause a decrease of the lumen of a blood vessel. Mostly this does not cause any clinical symptoms, as long as the blood vessel is not completely obliterated. However, the layer of connective tissue separating the plaque from the lumen can rupture, so that the fatty content of the plaque will come in contact with the blood. This will cause the formation of a thrombus at the place of the rupture, which can obliterate the lumen. It can also occur that (part) of the thrombus will propagate and obliterate a smaller vessel. In both cases, the tissue behind the obliteration will be deprived from blood and oxygen, which can lead to tissue damage or cell death (infarction). In atherosclerosis of the carotid arteries, it will cause a TIA, or even worse, a stroke.
Patients who have had a TIA (transient ischemic attack of the brain) or stroke will undergo a standard ultrasound examination to assess the presence of atherosclerosis of the carotid arteries. At this examination, the degree of stenosis will be measured using acoustic waves. If the degree of stenosis is more than 70%, the vascular surgeon will decide (in consultance with the patient and the neurologist) to surgically remove the plaque , because of the high risk of (recurrent) stroke.
However, research has shown that the composition of the plaque may be even more

important than the degree of stenosis which is caused by it; a plaque which causes only little stenosis may still be very vulnerable. Besides the accumulation of fat, smooth muscle cells and connective tissue, growth of new small blood vessels (neovascularisation) often occurs in a plaque. Neovascularisation may be an important factor contributing to plaque vulnerability. A standard ultrasound examination cannot depict neovascularisation in a plaque. An ultrasound examination using a contrast agent (contrast-enhanced ultrasound), however, may be able to do so. Magnetic resonance imaging (MRI) has shown to be able to make detailed pictures of the carotid artery. However, it is still unknown whether both contrast-enhanced ultrasound and MRI are able to depict neovascularisation in a plaque.

## Study objective

The purpose of this study is to investigate whether contrast-enhanced ultrasound and/or MRI are able to depict neovascularisation in atherosclerotic lesions (plaques) of the carotid artery. If contrast-enhannced ultrasound and/or MRI are able to do so, subsequent studies can investigate whether patients in whom neovascularisation has been diagnosed (by these imaging modalities), indeed are at higher risk of developing a stroke. These patients would then be eligible for extra and/or earlier therapy to prevent a (recurrent) stroke.

## Study design

This is a diagnostic study.
Findings of pre-operative contrast-enhanced ultrasound and MRI will be compared to the results of histopathological analysis of (resected) plaques of the carotid artery.

## Study burden and risks

Burden
-The length of contrast-enhanced ultrasound is approximately 45 minutes, and patients will lay on a bed during this examination. The patient will not feel anything of the imaging procedure.
-During the MRI examination, patients way lay on their back for approximately 45 minutes. This may be inconvenient for patients with back problems. The patient will not feel anything of the imaging procedure. The MRI scanner will make a lot of noise during the examination, which can be inconvenient. To overcome this, patients will use earplugs or earphones. The MRI scanner is a kind of tube, which is open at he front and at the rear end. Still, some people may find it inconvenient to lay is such a *tube*.
It will be attempted to plan both examinations (contrast-enhanced ultrasound and MRI) at the same day. If this is not possible, each of the examinations will take place on separate days (in consultance with the patient).

Risks
-Contrast-enhanced ultrasound uses acoustic waves which are harmless. Adverse effects of the contrast agent used (SonoVue) are uncommon, among which headache and nausea. A rare adverse effect is the occurrence of an allergic reaction and shock. Therefore, participating patients should remain in the hospital (under observation) up to half an hour after administration of the contrast agent. At the site of the injection of the contrast agent, a temporarily sensitive area may occur, along with some swelling the occurrence of a blue bruise. Very seldom, an infection occurs at this site.
-MRI does not use ionising radiation and is not dangerous. However, patients with pacemakers, metallic implants, vascular clips or metallic eye fragments may not participate in this study. The adverse effects of the MRI contrast agent (Magnevist) 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 adverse 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. At the site of the injection of the contrast agent, a temporarily sensitive area may occur, along with some swelling the occurrence of a blue bruise. Very seldom, an infection occurs at this site.

# 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

-Subjects with a >70% carotid artery stenosis who are scheduled for carotid endarterectomy.
-Age 18 years or older

## Exclusion criteria

-Patients with acute coronary syndrome or clinically unstable ischaemic cardiac disease.
-Patients with right-to-left shunts, severe pulmonary hypertension, uncontrolled systemic hypertension, and adult respiratory distress syndrome.
-Pregnant and lactating women
-Patients with documented allergy to contrast media or a renal clearance <30 ml/minute
-Standard contra-indications for MRI (ferromagnetic implants like pacemakers or other electronic implants, metallic eye fragments, vascular clips, claustrophobia, etc).

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-03-2009 |
| Enrollment: | 18 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | SonoVue |
| Generic name: | sulphur hexafluoride |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 17-03-2008 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 28-04-2008 |
| Application type: | First submission |
| 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 |
|---|---|
| EudraCT | EUCTR2008-001318-25-NL |
| CCMO | NL21566.068.08 |
| Other | nummer wordt aangevraagd |