

ECG-gated Dual Source CT angiography (ECG-DSCTA) of the carotid arteries: the relationship between the stenotic grade and the arterial distensibility and evaluation of the image quality

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1) to assess the distensibility of carotid arteries and to relate the distensibility to the presence of atherosclerosis.2) to assess the image quality of motion free reconstructed images with ECG-gated CT scans.

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

Summary

ID

NL-OMON30823

Source

ToetsingOnline

Brief title

ECG-gated Dual Source CTA (ECG-DSCTA) of the carotid arteries

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

atherosclerotic disease in the carotid artery

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: arterial stiffness, Atherosclerosis, carotid artery, computed tomography

Outcome measures

Primary outcome

Arterial stiffness and the relationship with severity of stenosis.

Secondary outcome

Image quality.

Study description

Background summary

With a new CT scanner it is not only possible to detect atherosclerosis but also to assess the distensibility of the carotid artery.

The distensibility can decrease due to atherosclerosis.

Study objective

- 1) to assess the distensibility of carotid arteries and to relate the distensibility to the presence of atherosclerosis.
- 2) to assess the image quality of motion free reconstructed images with ECG-gated CT scans.

Study design

120 patients will participate in this study.

Patients who have to undergo a CT scan of the neck because of their symptoms will be asked to participate in this study.

The study will immediately be performed after the clinical scan. The study will take place on the same CT scanner and takes ten minutes.

Study burden and risks

This extra CT scan takes more or less ten minutes of time and the patient will be laying down on the scanner table.
The patient will receive an extra intravenous injection of contrast material.
There is a small risk of anaphylactic response to the contrast material.
The extra radiation dose that will be given is limited within the international accepted standards.

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 (TIA, minor stroke) in the last six months
- Signed informed consent
- clinical indication to undergo MDCTA of the carotid artery.
- at least 50 years old

Exclusion criteria

- Women who are pregnant or lactating.
- Patients who are hemodynamically unstable.
- Having any physical or mental status that interferes with the informed consent procedure.
- Presenting with history of anaphylactoid or anaphylactic reaction to contrast agents.
- Having a history of renal transplant.
- Severe renal impairment (kreatinine > 150 mmol/l).
- Not being able to remain lying down for at least 15-20 min (e.g. patients with unstable angina, dyspnea at rest, severe pain at rest, severe back pain).

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-02-2007

Enrollment: 120

Type: Actual

Ethics review

Approved WMO

Date: 25-01-2007

Application type: First submission

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	NL15018.078.06