CTA of the abdominal aorta at 80 kV and 100 kV and reduced contrast medium

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The goal of this study is to reduce the effective radiation dose and improve the image quality by a personalized amount of contrast medium in CTA of the abdominal aorta.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON42222

Source
ToetsingOnline

Brief title
CTA5

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Bloodvessel deviations

Research involving
Human

Sponsors and support

Primary sponsor: Radiologie
Source(s) of monetary or material Support: Voor dit onderzoek is geen extra geld nodig. Het zijn onderzoeken voor patiënten die al staan ingepland.

Intervention

Keyword: Contrast medium reduction, CT angiography, Effective radiation dose, Test bolus

Outcome measures

Primary outcome

The amount of Hounsfield Units (HU) measured in the aorta at 30 positions from

the celiac trunk to the iliac arteries.

Secondary outcome

- The clinical usefulness of the CT scans, determined by 5 radiologists, scored

on a scale from 1 to 5.

- The effective radiation dose of the CT scan

- The contrast to noise ratio

- The signal to noise ratio

Study description

Background summary

Since the introduction of MDCT technology, CT angiography (CTA) has become a standard tool for the evaluation of disease of the aorta and its major branches. As the use of MDCT has become routine in clinical practice, concerns have been raised regarding radiation exposure. The current literature assumes a small but not negligible risk for radiation induced cancer from CT examinations. With still an increasing number of CT examinations yearly, reduction of the radiation dose from CT is an important issue.

Lowering the tube voltage represents an important radiation reduction approach because the radiation dose varies with the square of the tube voltage. Hence, lowering the tube kilo voltage (kV) can substantially increase the contrast enhancement of vascular structures while simultaneously reducing radiation dose to the patient. The downside of low tube potential CT is the nonlinear increase in image noise, therefore it is necessary to adjust the CT tube current in order to maintain a constant image quality.

In our latest study *Abdominal aorta CTA at 80 kV and a reduced amount of contrast medium: A comparative analysis of image quality and radiation dose* the quantitative and qualitative results showed that more patients could be scanned with the use of 80 kV and the use of 30 mL of contrast medium instead of the clinical standard (120 kV and the use of 50 mL of contrast medium). The 80 kV images showed more image noise, however this did not resulted in diminished subjective image quality, as the increased attenuation of the iodinated contrast medium and the high attenuation difference between the arterial system and the poorly enhanced surrounding tissues can partially offset the greater image noise.

In a previously performed study we used a test bolus injection protocol with a test bolus of 10 mL contrast medium to synchronize the data acquisition with the arrival of contrast material in the abdominal aorta. The test bolus was followed by a diagnostic bolus injection of 20 mL 1:1 with saline diluted contrast medium. This resulted in a total contrast medium volume injection of 30 mL ioversol 350. It is widely accepted that heavy patients need more contrast medium than slim individuals to reach the same vessel enhancement. To personalize the amount of contrast medium of the diagnostic bolus, the diagnostic bolus in both BMI groups will be based on the *Lean body mass* (LBM) of the patients. The LBM is used as the basis to calculate contrast material dose for CTA, because LBM reflects the blood vessel volume better than a dose based on the patients weight in kilograms.

Study objective

The goal of this study is to reduce the effective radiation dose and improve the image quality by a personalized amount of contrast medium in CTA of the abdominal aorta.

Study design

Intervention study, feasibility study

Intervention

In total 90 patients who are referred for a CTA of the abdominal aorta according to clinical indications will be included. The patients will be divided into the low- (BMI < 28 kg/m2) and high- (BMI >= 28 kg/m2) body mass index (BMI) group. The patients will be scanned with the following CT scan parameters:
• Low BMI group scan with 80 kV
• High BMI group scan with 100 kV

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Based on the results of our previous performed study, the diagnostic bolus in patients in the low BMI group will be dosed with 0.4 mL of iodinated contrast medium per LBM. Patients in the high BMI group will be dosed with 0.6 mL of iodinated contrast medium per LBM. The diagnostic bolus injection will be diluted 1:1 with a saline chasing bolus.

Study burden and risks

There is a risk that the scans of the patients in the low BMI protocol will be of less quality, since less kV is used. Worst case scenario is that the patient will have to undergo a second scan. Immediately after scanning the patients, the scans will be looked after a radiologist to see if the image quality is sufficient. So when the image quality is not sufficient, patients will be scanned immediately and an additional needle prick is not necessary.

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

- Referred for CTA if the abdominal aorta according to clinical indications
- Mentally competent
- Signed informed consent
- > 18 years
- Kidney function > 45 GRF

Exclusion criteria

- Allergy contrast medium
- Known arrhythmias or other heart disorders
- Pregnancy or lactation

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2014
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	14-07-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-03-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL49139.028.14